EXHIBIT A

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CITY OF CHICAGO,

a municipal corporation,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; and ACTAVIS PLC,

Defendants.

Case No.:
JURY TRIAL DEMANDED

COMPLAINT*

Plaintiff City of Chicago, by its attorney, Stephen R. Patton, Corporation Counsel of the City of Chicago, for its Complaint against Defendants Purdue Pharma L.P., Purdue Phama Inc., the Purdue Frederick Company, Inc., Teva Pharmaceutical Industries, Ltd., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., and Actavis plc (collectively, "Defendants"), alleges as follows:

TABLE OF CONTENTS

*Redacted Pursuant to Confidentiality Agreements

I. INTRODUCTION

1. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. When marketing a drug, a pharmaceutical manufacturer must tell the truth, which means ensuring that its marketing claims are supported by science and medical experience. Defendants broke these simple rules.

2. By the 1990s, Defendants had the ability to cheaply produce massive quantities of opium-like painkillers ("opioids"), but the market was small. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. They knew – and had known for years – that opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain (pain lasting three months or longer), particularly because their effectiveness waned with prolonged use and because of the substantial risk of significant side effects and addiction, especially with high-dose use.[1] They also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (e.g., hospitals), where the risk of addiction and other adverse outcomes was much less significant.

3. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[2] Like heroin, prescription opioids work by binding to receptors on the

[1] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Research & Mgmt., 247-287, (H.L. Fields and J.C. Liebeskind eds., 1994).

[2] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin),

spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and, ultimately, death.

4. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea-change in medical and public perception that would permit the use of opioids for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches. Defendants, through a common, sophisticated, and deeply deceptive marketing campaign that continues to the present, set out to, and did, reverse the popular and medical understanding of opioids.

5. Beginning over 20 years ago, Defendants seized on anecdotal accounts of opioid use to treat chronic pain to begin a reeducation campaign about opioids. They spent millions of dollars funding, assisting, and encouraging doctors and front groups that would pioneer a new and far broader market for their potent and highly addictive drugs – the chronic pain market. Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids. They overstated the benefits of using opioids long-term to treat chronic non-cancer pain, promising improvement in patients' function and quality of life, and dismissed or minimized the serious risks and adverse outcomes of chronic opioid use, including the risk of addiction, overdose, and death. There was and is no reliable scientific evidence supporting Defendants' marketing claims, and there is a

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fentanyl (Duragesic, Fentora), heroin, methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone).

Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II.

wealth of scientific evidence to the contrary. They also deceptively marketed the drugs for indications and benefits that were prohibited by the drugs' labels.

6. Defendants' efforts were wildly successful. The United States is now awash in opioids. In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits result in the prescription of an opioid (nearly double the rate in 2000).[3] Opioids – once a niche drug – are now the most prescribed class of drugs – more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they have consumed 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.[4] Together, opioids generated $8 billion in revenue for drug companies in 2010.

7. Roughly 87% of these prescriptions are for chronic opioid therapy[5] – a prescribing practice doctors previously considered not just ineffective, but even reckless given the substantial risk of addiction chronic opioid use creates.

8. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic." Prescription opioid use contributed to 16,651 overdose deaths nationally in 2010 – more than twice as many deaths as heroin and cocaine combined and surpassing motor vehicle accidents as a cause of death. For every death, more than 30 individuals are treated in the emergency room. The U.S. Department of Health estimated that in 2009 in Chicago, there were

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[3] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51(10) Medical Care, 870-878 (2013).

[4] Laxmaiah Manchikanti et al., *Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective*, 13 Pain Physician, 401-435 (2010).

[5] Michael Von Korff, Group Health Res. Inst., "The Epidemiology of Use of Analgesics for Chronic Pain," Presentation to the FDA (2012), *available at*, http://www.fda.gov/downloads/Drugs/NewsEvents/UCM308128.pdf

40.4 emergency department visits involving adverse reactions to opioids per 100,000 people, which, for Chicago's population, translates into 1,080 trips to the emergency room.[6] But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

9. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors or from the secondary criminal market, and a pipeline of drugs that can be diverted to supply them. Sixty percent of opioid abusers report that their drugs came originally from prescriptions.[7] According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in the past year, and adolescents are abusing opioids in alarming numbers. Sixty percent of opioid abusers report that their drugs came originally from prescriptions.[8] The former president of the New Hope Recovery Center on the City's North Side stated: "Five years ago, 70 percent of the people we saw were heroin addicts. Today, 70 percent of the people we see are prescription drug users."[9]

10. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, which has imposed additional burdens on the City and local agencies that address heroin use and addiction. Chicago ranks first in the nation in heroin overdose deaths.[10] Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost

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[6] *Metro Brief Chicago: Drug-Related Emergency Dep't Visits in Metro. Areas*, U.S. Dep't of Health and Human Servs.: Substance Abuse & Mental Health Servs. Admin. (2009), http://www.samhsa.gov/data/StatesInBrief/2k9/CityReports/Chicago_IL.pdf

[7] Nathaniel Katz, *Opioids After Thousands of Years, Still Getting to Know You*, 23 The Clinical Journal of Pain, 303-306 (2007).

[8] *Id.*

[9] Monifa Thomas, *Prescription Drug Abuse Is Fastest-Growing Drug Problem in Country*, Chicago Sun-Times (Sept. 24, 2012), www.suntimes.com/2989811-417/drug-abuse-prescription-drugs-pain.html.

[10] Natalie Mooer, *Heroin: It's Cheap, It's Available and It's Dangerous Business*, WBEZ 91.5, (Dec. 14, 2013), http://www.wbez.org/news/heroin-its-cheap-its-available-and-its-dangerous-business-109304.

$10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person started on prescription opioids for a back injury, to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

11. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and the former White House drug czar, opines that opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[11]

12. To shift medical convention and unleash this epidemic, Defendants engaged in a campaign of deception that: (1) misrepresented the efficacy of opioids, (2) trivialized or obscured their serious risks and adverse outcomes, and (3) overstated their superiority, compared with other treatments. Defendants supported, encouraged, and directed employees, front groups, and doctors they identified as "Key Opinion Leaders" ("KOLs") to publicize biased and misleading studies and promotional materials and conduct thousands of medical education programs that were deceptive and lacked balance. These "educational" efforts were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors and patients that the benefits of using opioids to treat chronic non-cancer pain outweighed their risks and that opioids could be used safely by most patients.

13. Defendants' representations regarding the benefits, risks, and relative superiority of opioids were – and are – untrue and unsupported by competent scientific evidence. In fact, even Defendants' KOLs initially were very cautious about whether opioids were safe and

[11] Transcript of Use and Abuse of Prescription Painkillers, The Diane Rehm Show (Apr. 21, 2011), http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript.

effective to treat chronic non-cancer pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers and physicians who have sounded the alarm on the long-term use of opioids to treat chronic non-cancer pain, Defendants continue to disseminate their false and misleading marketing claims even today.

14. Defendants' marketing not only ignored contrary evidence, but also failed to acknowledge risks disclosed on their own labels and sometimes exceeded the approved indications. Defendant Cephalon, for example, marketed its opioid Fentora for chronic non-cancer pain even though it was approved only to treat cancer pain. Defendants also promised that opioids would improve patients' ability to function, even though such benefits had not been proven and were specifically disputed by the FDA.

15. Many of Defendants' strategies are modeled on promotional activities that have been deemed unlawful and for which the drug companies have paid billions of dollars in settlements and judgments. What makes this effort particularly nefarious – and dangerous – is that unlike most other prescription drugs, opioids are highly-addictive controlled substances. Defendants deceptively engaged a patient base that – physically and psychologically – could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

16. Countless Chicagoans suffer from chronic non-cancer pain, which takes an enormous toll on their health, their lives, and their families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived Chicago patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payers of the chance to exercise informed judgment and subjected them to enormous suffering and costs.

17. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Fentora's label) may have allowed or did not exclude the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids; if that were the case, there would be few limits on what a drug company could say about its product.

18. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness, and indeed hijack, what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

19. Defendants' course of conduct, individually and collectively, has violated and continues to violate local, state, and common law, as laid out below.

- Chicago Municipal Code § 2-25-090, in that Defendants engaged in fraudulent, unfair, and deceptive acts and practices, including misleading advertising in their promotion of opioids to treat chronic non-cancer pain, and/or engaged in conduct that violates the Illinois Consumer Fraud and Deceptive Business Practices Act and/or the Uniform Deceptive Trade Practices Act.

- Chicago Municipal Code § 4-276-470 in that Defendants employed deception, fraud, false pretense, false promise or misrepresentation, or concealed, suppressed or omitted material facts with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise.

- Chicago Municipal Code § 1-21-010 in that Defendants knowingly made false statements of material fact to the City in violation of any statute, ordinance or regulation, or knowingly made a false statement of material fact to the city in connection with any application, report, affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit.

- Chicago Municipal Code § 1-22-020, in that Defendants knowingly presented or caused to be presented to the City false or fraudulent claims for payment or approval;

knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the City; and/or conspired to defraud the City by getting false or fraudulent claims allowed or paid.

- Chicago Municipal Code Section § 1-20-020 in that Defendants caused the City or its agents to incur costs in order to provide services reasonably related to Defendants' violation of any federal, state or local law, and/or Defendants failed to correct conditions which violate any federal, state or local law that Defendants were under a legal duty to correct.

- 720 ILCS 5/170-10.5 in that Defendants knowingly obtained, attempted to obtain, or caused to be obtained, by deception, control over the property of a self-insured entity, the City, by making a false claim or by causing a false claim to be made to the City, intending to deprive the City permanently of the use and benefit of that property.

- The common law prohibition against civil conspiracy in that Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

- The prohibition against common law fraud in that Defendants made false statements of material fact that they knew were false to induce the City to act; the City relied on Defendants' false statements, relied on others who relied on Defendants' false statements, or both; and was damaged as a result.

- The common law prohibition on unjust enrichment in that Defendants have unjustly retained a benefit to the City's detriment, and Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

20. To redress and punish these violations, the City seeks a judgment requiring Defendants to pay restitution, damages, including multipliers of damages, disgorgement, civil penalties, punitive damages, and attorneys' fees, costs, and expenses, and any other relief to which the City may be entitled. The City also requests that the Court order Defendants to cease their unlawful promotion of opioids and to correct their misrepresentations.

II. PARTIES

A. Plaintiff

21. Plaintiff is the City of Chicago (the "City"), a municipal corporation organized and existing under the laws of the State of Illinois. The Corporation Counsel has the authority to "[a]ppear for and protect the rights and interests of the city in all actions, suits and proceedings brought by or against it or any city officer, board or department [.]" Chicago Municipal Code § 2-60-020.

B. Defendants

22. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware; Purdue Pharma, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut; and The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids, including OxyContin, its largest selling opioid, in both Chicago and the nation. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

23. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million – at the time, one of the largest settlements with a drug company for marketing misconduct. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

24. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Pharmaceutical Industries, Ltd. acquired Cepahlon, Inc. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. (Teva Pharmaceutical Industries, Ltd. and Cephalon,

Inc. are collectively referred to herein as "Cephalon".) Cephalon is in the business of manufacturing, selling and distributing pharmaceutical drugs, including opioids Actiq and Fentora, nationally and in Chicago.

25. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain "with malignancies who had developed a tolerance to less dangerous therapies." The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon plead guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

26. Cephalon also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The agreement, *inter alia*, required Cephalon to send doctors a letter advising them of the settlement terms and giving them a means to report questionable conduct of sales representatives; to post payments to doctors on its web site; and to regularly certify that the company has an effective compliance program.

27. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey (Janssen Pharmaceuticals, Inc. and Johnson & Johnson are collectively referred to herein as "Janssen"). Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in Chicago and nationally, including the opioids Duragesic, Nucynta, Nucynta ER, Ultracet, and Ultram. Duragesic is the largest selling opioid of the group. Sales of Janssen's opioids collectively commanded between $1.3 billion in revenue in 2009 and $1.2 billion in 2012 – a total of $4.7 billion dollars over the four-year period.

28. Defendant Endo Health Solutions Inc. ("Endo") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo develops, markets, and sells

prescription drugs, including opioids Opana, Percocet, and Percodan, in Chicago and throughout the United States. These opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana yielded revenue of $1.16 billion between 2008 and 2012, and alone accounted for 10% of Endo's total 2012 revenue.

29. Defendant Actavis plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012 and the combined company name was changed to Actavis, Inc. as of January 2013, and then Actavis plc in October 2013. Throughout the Complaint, "Actavis" collectively refers to Actavis, Inc. and Actavis plc. During the relevant time period, Actavis engaged in the business of marketing and selling opioids in Chicago and across the country, including the branded drug Kadian and generic versions of Duragesic and Opana.

III. JURISDICTION AND VENUE

30. Pursuant to the Illinois Constitution art. VI, § 9, this Court has subject matter jurisdiction over the City's claims..

31. This Court has personal jurisdiction over Defendants pursuant to 735 ILCS § 5/2-209(1) because Plaintiff is the City of Chicago, located within Illinois, and Defendants carry on a continuous and systematic part of their general business within Illinois, and have transacted substantial business in Illinois which has caused harm in Illinois.

32. Venue as to each Defendant is proper in Cook County because, pursuant to 735 ILCS § 5/2-108, part of the transactions out of which the asserted causes of action arise occurred in Cook County, Illinois.

IV. JURY DEMAND

33. Pursuant to 735 ILCS § 5/2-1105, the City demands a trial by jury.

V. FACTUAL ALLEGATIONS

A. Before Defendants' Deceptive Marketing Campaign, Opioids Were Rarely Prescribed by Physicians Because of Their Known Serious Side Effects and Substantial Risk of Addiction

34. Opioids have long been approved and accepted for the treatment of chronic cancer pain. Opioids are appropriate for this use given the severity of pain often associated with cancer and the recognition that the benefits of treating that pain outweigh the potential risk of addiction, especially for terminal patients. The same is not true for chronic non-cancer pain. Among other differences, the pathology responsible for cancer pain is distinct from these pathologies that cause chronic pain. For patients with cancer, the source of their pain is likely to be the tumor and pressure on, or erosion of nerves or bones. Chronic pain arises from multiple sources, including musculoskeletal (from joints, ligaments, or muscles), neuropathic (or nerve-related, occurring in diseases like diabetes or shingles), headache, or functional pain (arising from disease states such as irritable bowel) that respond differently—or not at all—to opioids.

35. However, over the past twenty years, fueled by aggressive marketing from the pharmaceutical industry, opioid use for the management of chronic non-cancer pain has become commonplace. As set forth below, use of opioids for long-term non-cancer pain management is based on "unsound science and blatant misinformation . . . and dangerous assumptions that opioids are highly effective and safe, and devoid of adverse events when prescribed by physicians."[12]

36. As admitted in 1994 by Dr. Russell Portenoy, a KOL who went on to tirelessly promote opioid therapy for the treatment of chronic non-cancer pain (also called chronic nonmalignant pain), the medical consensus before Defendants' "reeducation" campaign was decidedly against the use of opioids to treat chronic non-cancer pain:

> ***The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs***. This perspective has been justified by the perceived likelihood of

[12] Laxmaiah Manchikanti et al., *Opioid Epidemic in the United States*, 15(3 Suppl) Pain Physician, ES9-ES38 (July 2012).

> tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. ***Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects.*** There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.[13]

37. Dr. Portenoy left no doubt about the 1994 state of knowledge concerning the safety and efficacy of opioid therapy for long-term chronic non-cancer pain:

> At the present time, neither the medical literature nor clinical experience provides compelling evidence that long-term opioid use would be salutary for more than a very small number of patients with chronic nonmalignant pain . . .[14]

38. But the lack of any credible science supporting opioid therapy for chronic non-cancer pain did not stop Defendants from marketing opioid therapy for that use. Working with and through KOLs like Dr. Portenoy, Defendants seized on anecdotal accounts of opioid efficacy in limited populations and methodically, through numerous publications, programs, and spokespeople, overstated the benefits and understated the risks of opioids in order to create and defend a broad market for opioids that never should have and never would have come to exist absent Defendants' concerted, deliberate, and patently misleading efforts.

B. Defendants Are Obligated to Ensure that their Marketing is Truthful, Complete, and Balanced

39. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. Drug makers' claims in promotional materials must be supported by "substantial" scientific evidence and cannot be false or misleading. 21 U.S.C. § 352(a). The materials must reflect a "fair balance," accurately and

[13] Portenoy, *supra* note 1, at 247 (emphasis added).

[14] *Id*. at 278 (emphasis added).

comprehensively describing the risks and benefits of the drug, and cannot ignore or minimize a drug's risk or overstate its benefits. 21 CFR § 202.1(e)(6). Federal regulations bar affirmative claims that are untruthful, as well as the omission of material facts that make the drug-related information inaccurate. 21 CFR §§ 202.1(e)(3), 1.21(a). It is a violation of federal law for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study." 21 CFR § 99.101(a)(4).

40. Drug companies also must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience." 21 CFR § 202.1(e)(6)(ii). While the FDA must approve a drug's label — defined to include all explanatory material accompanying the label, 21 U.S.C. §§ 321 (k), (m) — it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information. *See* 21 CFR § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 CFR § 314.70(c)(2) (allowing manufacturers to make changes that "strengthen . . .a warning, precaution, or adverse reaction). In addition, while promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated, the FDA does not have to approve these materials in advance. If, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations that it deems less serious, while warning letters are reserved for violations that affect patients' safety or reflect continued violations of the law.

41. The federal regulatory framework reflects public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for making certain that prescribers have accurate and complete information so that

they can assess the risks and benefits of drugs for their patients to ensure their health and safety. The Chicago Consumer Fraud and False Claim ordinances reflect the same judgment that drug companies, like other businesses, have a duty to deal honestly with consumers, government, and other payers who purchase and use their products.

C. Defendants' Marketing of Opioids for Long-Term Use to Treat Chronic Non-Cancer Pain was False, Misleading, Imbalanced, and Unsupported by Science

42. For years, Defendants systematically violated state and local laws requiring that the promotion of pharmaceutical drugs, like other consumer products, not be false, deceptive, or misleading. Defendants manipulated and ignored scientific evidence to formulate and broadcast the misrepresentations described below, each of which was instrumental in: (1) overcoming longstanding medical and legal barriers to opioid therapy for chronic non-cancer pain; and (2) making high-dose, long-term opioid use the new "gold standard" of treatment of chronic non-cancer pain.

43. Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unbranded marketing materials—materials that generally promoted opioid use but did not name a specific opioid drug name. Upon information and belief, Defendants used these unbranded materials, which are not reviewed by the FDA, to disseminate messages that were inaccurate, were inconsistent with their branded marketing materials and the drugs' labels and package inserts, and would not pass muster with the FDA. Had they relied on branded materials, the FDA-required drug labels and package inserts would have been included to more fully describe the risks and administration of opioids.

44. Defendants marketed directly to patients to: (1) encourage them to ask doctors for opioids to relieve chronic non-cancer pain; and (2) allay their well-founded concerns that opioids were dangerous and addictive. Defendants targeted particularly vulnerable, but usually well-insured, groups of patients, such as veterans and the elderly. Defendants leveraged and funded patient organizations and communities – promoting opioids particularly for common conditions, such as headaches, arthritis, fibromyalgia, and back pain. Unlike other direct-to-

consumer marketing, Defendants, as a group, focused on unbranded advertising knowing that the creation of a new, expansive market for opioids would benefit all manufacturers.

45. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic non-cancer pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Through misleading medical education programs, treatment guidelines, and other efforts, Defendants "reeducated" general practitioners and family doctors. They knew that these doctors reach the vast majority of patients with common chronic pain complaints, but are less likely than specialists to have the time or knowledge to evaluate Defendants' deceptive messages or to closely monitor patients for signs of improvement or adverse outcomes (such as addiction).

46. Individually and collectively, Defendants developed, disseminated and promoted a series of misrepresentations aimed broadly at reversing the ultimately well-founded fears and beliefs of doctors and patients.

1. Defendants' misrepresentations regarding the benefits of opioids for chronic non-cancer pain.

47. Defendants deceptively promoted opioids as improving chronic non-cancer patients' function by allowing them to get back to "normal" and reducing their pain long-term. Defendants misrepresented the efficacy of opioids in an effort to persuade doctors and patients that their benefits outweigh their risks.

48. Although opioids may initially improve patients' function by providing pain relief in the short term, there were – and are – no controlled studies of the use of opioids beyond 16 weeks and no evidence that opioids improve patients' function long-term. Indeed, research such as a 2008 study in *Spine* has shown that pain sufferers prescribed opioids long-term suffered

addiction that made them more likely to be disabled and unable to work.[15] Despite this lack of evidence — and evidence to the contrary — Defendants consistently promoted opioids as capable of improving patients' function and quality of life.

49. The FDA has recognized that claims that opioids improve patients' function are misleading. For example, a company claimed that its opioid "Improved Overall Function," offered "Long Lasting Improvements in Physical Function," and would enable patients to be better able to engage in a list of daily activities, such as walking, standing, and climbing stairs. In a warning letter sent March 24, 2008, the FDA publicly made clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities … has not been demonstrated by substantial evidence or substantial clinical experience."

50. In marketing Kadian, Actavis made implied claims that the drug would allow chronic non-cancer pain patients to return to work, relieve "stress on your body and your mental health," and help them enjoy their lives. The FDA found that Actavis misrepresented the scientific evidence: "[W]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[16]

51. Defendant Janssen also distributed a series of posters to doctors' offices that showed pictures of people dressed for a variety of active professions suggesting that doctors prescribe Ultracet because "Pain doesn't fit into their schedules." Despite the lack of scientific evidence in support of such a claim, the posters falsely implied that Ultracet was appropriate for

[15] Jeffrey Dersh et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine, 2219-2227 (Sept. 15, 2008).

[16] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18. 2010).

help in maintaining an active lifestyle. Several of the posters contained the tagline "Ultracet lets them perform."

52. In spite of the complete lack of scientific basis, in 2011, Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, published by the American Pain Foundation ("APF"), which asserted that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic non-cancer pain patients. To support this claim, APF cited *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, a study published in 2006 in the Canadian Medical Association Journal. However, the study concludes: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The Purdue-sponsored *Guide* failed to disclose this conclusion, as well as the fact that the study was conducted only for five weeks, and therefore could not support the long-term use of opioids, or the study's findings that opioids were actually less effective than alternative treatments.

53. [redacted] In 2009, one of its marquee components was a "first-of-its-kind" Web-based series, called *Let's Talk Pain,* hosted by veteran TV journalist Carol Martin. [redacted]

54. The *Let's Talk Pain* talk show—which is still available online—[redacted]

[redacted]. In the very first episode of this talk show, the following exchange, from a script edited and approved by Janssen, took place:

> **Teresa Shaffer (APF Action Network Leader)**: As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> **Dr. Al Anderson (AAPM Board of Directors)**: The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor when they are suffering from pain for a long period of time, especially moderate to severe pain. And that's the patients that we really need to use the opioids methods of treatment, because they are the ones who need to have some help with the function and they're the ones who need to have their pain controlled enough so that they can increase their quality of life.
>
> **Teresa Shaffer**: This is what has allowed me to continue to function and is what has allowed me to have somewhat of a normal life, is the opioids.[17]

There simply is no scientific evidence that opioids taken long-term improve function or quality of life for chronic non-cancer pain patients, and significant evidence that opioids impose significant risks and adverse outcomes on long-term users, none of which is disclosed in this video interview.

55. Similarly, the National Initiative on Pain Control ("NIPC"), an APF initiative [redacted] ran a facially unaffiliated website called www.painknowledge.org. NIPC billed itself as "an integrated education initiative" and promoted its expert leadership team, including "nationally respected experts in the pain management field." [redacted] Painknowledge.org promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able

[17] Let's Talk Pain, *Episode 1: Safe Use of Opioids (PainSAFE)*, YouTube (Sept. 28, 2010), http://www.youtube.com/watch?v=zeAlVAMRgsk (0:35 to 1:09).

to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy.

56. Endo also advertised its Opana ER (or extended release) drug by depicting a professional chef and a construction worker, each with chronic lower back pain, smiling and working as a result of Opana ER.

57. [redacted]

58. Defendants' misrepresentations about increased function are particularly misleading for specific indications for which they promoted opioids, such as migraines and lower back pain. For instance, research indicates that as many as 30% of patients who suffer from migraines have used opioids to treat their headaches.[18] Despite this, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.[19] A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[20] Studies of the use of opioids long-term for chronic lower back pain similarly have been unable to demonstrate an improvement in patients' function.[21]

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[18] Dawn C. Buse, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, 52 Headache: The Journal of Head & Face Pain, 18-36 (Jan. 2012).

[19] *Id.*

[20] *Press Kits – Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment*, National Headache Foundation (May 15, 2007), http://www.headaches.org/press/NHF_Press_Kits/Press_Kits_-_Migraine_Patients_Taking_Addictive_Or_Non_Approved_FDA_Migraine_Treatments.

[21] Luis E. Chaparro, *Opioids compared to placebo or other treatments for chronic low-back pain*, 8 Cochrane Database of Systematic Reviews (2013).

59. There also is evidence that, over the long-term, opioid therapy fails to lessen, and sometimes increases, patients' pain – important facts that Defendants fail to include in their marketing literature. For example, Defendants have failed to disclose scientific evidence that establishes that many patients on chronic opioid therapy continue to experience significant pain and dysfunction.[22] Defendants also have failed to disclose research and clinical experience demonstrating that: (1) the analgesic (pain relieving) efficacy of opioids often declines over time; (2) patients on opioids long-term may develop greater sensitivity to pain ("hyperalgesia"); and (3) because they develop tolerance to the medication over time, many chronic non-cancer pain patients require ever higher doses of opioids to obtain relief and are on doses that doctors have described as "frighteningly high."[23]

60. Consistently, in their marketing, Defendants failed to disclose the lack of evidence to establish that opioids are safe and effective long-term, as well as the growing body of evidence that the risks of opioids increase and their benefits decline over time. The studies relied on by Defendants in marketing their drugs are short-term, typically for less than 12 weeks. For example, an ad that Janssen currently is running, including on its website, claims that Nucynta ER has "Efficacy you need, Tolerability you want." However, each of the studies included in the drugs approval were only conducted over a 12-week period, using a pre-seeded patient group; thus none provide support for a claim of long-term efficacy in the population at large. Indeed, Janssen also failed to disclose that it submitted a fourth study for the FDA's

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[22] Mark D. Sullivan et al., *Problems and concerns of patients receiving chronic opioid therapy for chronic non-cancer pain*, 149(2) Pain, 345-353 (2010); Jørgen Erikson et al., *Critical issues on opioids in chronic non-cancer pain*, 125(1-2) Pain, 172-179 (2006); *see also*, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*, Institute of Med. Comm. on Advancing Pain Research, Care, & Educ. Board on Health Sci. Policy, (2011). K.S. Dillie et al., *Quality of life associated with daily opioid therapy in a primary care chronic pain sample*, 21(2) Journal of the Am. Bd. Of Family Med., 108-117 (Mar.-Apr., 2008).

[23] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med., 1422-1424 (Sept. 13, 2010).

consideration that did not show pain reduction over placebo and was thus omitted from the approval.

61. As a pain specialist noted in an article titled, *Are We Making Pain Patients Worse?*, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." Instead, at higher doses, patients are much more likely to develop dependence or addiction, experience pain deterioration due to hyperalgesia, and are three to nine times more likely to die from opioid-related causes than those on low doses.[24] Additionally, epidemiological data suggest that only a minority of patients on chronic opioid therapy benefit from the drugs and most continue to suffer significant pain and limitations on their activities. Defendants have never disclosed these facts.

2. Defendants' misrepresentations regarding the adverse outcomes and risks of opioids.

62. In an effort to persuade doctors to prescribe opioids for chronic non-cancer pain, Defendants deceptively overstated the safety and minimized the adverse outcomes, particularly the risk of addiction and abuse from using opioids long-term.

a. Risk of addiction and abuse.

63. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic non-cancer pain patients, Defendants had to overcome

[24] Tara Gomes et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain*, 171(17) Archives of Internal Med., 686-691 (Apr. 11, 2011); Kate M. Dunn et al. *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med., 85-92 (Jan. 19, 2010).Most overdoses were medically serious and 12% were fatal. *Id*. *See also* J.B. Braden et al., *Emergency Department visits among recipients of chronic opioid therapy*, 170(16) Archives of Internal Med., 1425-1432 (Sept. 13, 2010) (finding that higher doses of opioids doubled the risk of adverse drug events).

doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk – condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic non-cancer pain conditions sufficient to justify that risk would have posed a nearly insurmountable challenge.

64. Remarkably, Defendants were able to do it; even though opioids are controlled substances – classified under the federal Controlled Substances Act as having "high potential for abuse" and a "risk of severe psychological and physical dependence."[25] Defendants: (1) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (2) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk – and Defendants' own FDA labels – compelled disclosure.

65. Contrary to Defendants' claims, numerous studies support that, though these patients may not presently show signs of abuse or addiction, at least 15% and as many as 40% of patients will become addicted to opioids.[26] Research has shown that opioids are even more addictive than cocaine and alcohol. One in three to five users who self-administer short-acting opioids will become addicted, versus one in eight to fifteen for users of cocaine or alcohol.[27]

(1) Minimizing the risk of addiction.

[25] 21 U.S.C. § 812(b).

[26] (*E.g.*, Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction, 1776-1782 (Oct. 2010); Joseph A. Boscarino et al., *Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria*, 30(3) Journal of Addictive Diseases, 185-194 (July-Sept., 2011); *Prescription Drugs: Abuse and Addiction,* National Inst. on Drug Abuse, (Oct. 2011), http://www.drugabuse.gov/sites/default/files/rrprescription.pdf.)

[27] Mary J. Kreek et al., *Pharmacotherapy of Addictions*, 1(9) Nature Reviews: Drug Discovery, 710-726 (Sept. 2002).

66. Local pain specialists interviewed by the City indicated that sales representatives, or detailers, employed by drug companies, never talked to them about the risk of addiction from long-term use of opioids.

67. Nor did their marketing materials portray the risk of abuse or addiction. As discussed below, Defendants omitted addiction from the list of adverse outcomes they disclosed. In addition, to the extent they discussed addiction, they described it as "rare" or not an issue for pain patients, as opposed to illicit users.

68. For example, in a Janssen- sponsored publication, *Finding Relief: Pain Management for Older Adults,* published in 2009 and still available online, Janssen asserts as "Fact" that "opioids are *rarely* addictive when used properly for the management of chronic pain." (Emphasis in the original.) [redacted]

69. Similarly, Endo promised on a website it funded, that "People who take opioids as prescribed usually do not become addicted."

70. Defendants' efforts to minimize the risk of addiction from taking opioids long-term are evident in the contrast between their unbranded materials, which dramatically understate or deny the risk of addiction, and branded materials, which include stronger addiction warnings taken from the drugs' labels. Defendants took advantage of the less-monitored unbranded marketing channel to disseminate their deceptive messages regarding the risk of addiction from long-term opioid use. For example (emphasis added):

		Opana ER Advertisement (2011/2012/2013)
[redacted]	[redacted]	branded Endo advertisement
[redacted]	[redacted]	"[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other

	[redacted]	opioid agonists, legal or illicit." "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

71. Defendants also falsely reassured doctors and patients that, when taken properly under a doctor's supervision, opioids would not become addictive. Defendants' representations that opioid addiction can be effectively managed by competent physicians not only had the effect of increasing the number of opioid prescriptions, but deflected the responsibility from Defendants' marketing to doctors' prescribing and treatment practices.

72. Defendants deceptively downplayed the risk of addiction for chronic pain patients by defining opioid addicts as people who get the drugs illicitly and take them improperly – not patients taking drugs they were prescribed. According to Defendants, patients who take opioids prescribed to them are not addicted.

73. A 2004 Endo patient education publication, edited by KOL Dr. Russell Portenoy, and titled, *Understanding Your Pain: Taking Oral Opioid Analgesics*, which is still available online, answers the hypothetical patient question — "What should I know about opioids and addiction?" — by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that, "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction."

74. [redacted]

75. More graphically, a Purdue brochure, still provided to doctors today, called *Indications of Possible Drug Abuse*; shows pictures of the stigmata of injecting or snorting

opioids – skin popping, track marks, or perforated nasal septa.[28] In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassure doctors that as long as they did not observe those signs, they need not worry that their patients were abusing or addicted to opioids.

76. These deceptive messages gave doctors and patients a false sense of security that as long as patients are only taking opioids a doctor gives them – regardless of the dose or frequency ingested– and not manipulating them, snorting, or injecting them, they are not addicted. That is dangerously false Many opioid users who become addicted to the drugs began using them when a doctor prescribed them. Pain patients and opioid addicts are not separate universes, but overlapping circles. As one study noted, "a potential side effect from chronic use can be abuse and addiction … [I]n fact, correct use and abuse of these agents are not polar opposites – they are complex, inter-related phenomena."[29] A review of studies of urine drug monitoring for opioid patients showed that at least 11% of patients with chronic non-cancer pain were misusing opioids and at least 12% were not taking their medication as prescribed.[30]

77. Dr. Scott Fishman, another KOL whose work was long supported by opioid makers, acknowledged that data supporting the contention that addiction is rare:

> [The data] have been found to be inadequate and seriously flawed. Although we currently do not know the exact rate of addiction in patients legitimately prescribed opioids for pain or the rate of overall misuse, we know that rates are high enough that they should be considered a significant potential adverse effect.[31]

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[28] *Providing Relief, Preventing Abuse: A reference guide to controlled substance prescribing practices*, Purdue Pharma L.P. (Stamford, C.T.), 2nd ed. 2011, at 13.

[29] Wilson M. Compton & Nora D. Volkow, *Major increases in opioid analgesic abuse in the United States: concerns and strategies*, 81(2) Drug and Alcohol Dependence 103, 106 (Feb. 1, 2006).

[30] Nathaniel P. Katz et al., *Prescription Opioid Abuse: Challenges & Opportunities for Payers*, 19(4) Am. Journal of Managed Care 295, 301 (2013).

[31] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide*, 15, The Fed'n of State Med. Bds. Found., 2nd ed. (2012).

78. Relatedly, at least Endo, and potentially other Defendants, sought to minimize the risk of abuse by misrepresenting their drugs' susceptibility to tampering. In 2012, Endo asked the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, meaning that it was protected against manipulation that would allow users to snort or inject it. It also sought permission to withdraw its previous approval for Opana ER in favor of its newer, purportedly safer version. The FDA denied both requests, explaining in a May 10, 2013 letter that there was no evidence the new design "would provide a reduction in oral, intranasal or intravenous abuse" and that Endo's "postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse[.]" Yet, Endo advertised, and advised its sales representatives and speakers' bureau doctors, to market reformulated Opana ER as "the only oxymorphone extended release tablets that are *designed to be crush resistant*." (Emphasis added.) Endo chose its words carefully, but the misleading impression it created – that Opana is tamper-resistant and therefore less subject to abuse – was no doubt deliberate.

(2) Claiming the risk of addiction can be identified and managed.

79. Defendants continue to maintain to this day that *most* patients safely can take opioids long-term for chronic non-cancer pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, Defendants have come to admit that *some* patients *could* become addicted. But, more recently, Defendants claim that opioid addiction can be avoided if doctors use screening tools or questionnaires that identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse).[32]

80. There are three fundamental flaws in Defendants' assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that

[32] The FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics directs doctors to "assess each patients' risk of abuse." However, it does not excuse drug companies' misrepresentations that the screening tools allow them to prevent low-risk or high-risk patients from abusing or becoming addicted to opioids.

screening works to substantially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients can be given opioids safely, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients without red flags can take opioids long-term without significant danger of addiction.

81. Yet Defendants made assurances about addiction and screening anyway. [redacted]

82. Dr. Russell Portenoy, a pro-opioid, Defendant-funded KOL, appeared on *Good Morning America*, in 2010, to discuss the use of opioids long-term to treat chronic non-cancer pain. He claimed that, "[a]ddiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

83. A Cephalon-sponsored guide, *Opioid Medications and REMS: A Patient's Guide*, similarly claimed: "Some people are nervous about taking opioids because they are afraid they will become addicted. However, patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

84. Pro-opioid KOL Lynn Webster developed a basic five-question risk screening tool called the Opioid Risk Tool. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to doctors in Chicago during the relevant period.

85. An Endo-sponsored 2007 supplement to the *Journal of Family Practice* contained an article written by a Chicago doctor who was on all of Defendants' speakers' bureaus, *Pain Management Dilemmas in Primary Care: Use of Opioids*, which recommended risk screening

through the use of the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain. The author claimed that even patients at high risk of addiction could be safely treated with opioids through "a maximally structured approach" including toxicology screens and pill counts.

86. In 2012, the same Chicago KOL also presented at a Purdue-sponsored continuing medical education program ("CME"), *Chronic Pain Managing and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, in which he discussed the treatment of a high-risk chronic pain patient demonstrating signs of opioid addiction. The presentation recommended that doctors facing a similar patient, again, use risk screening tools. He also taught that doctors should consider reducing the prescription fills and switching to a different opioid as management strategies. Regardless of steps taken, the message was to continue opioid therapy.

87. Many of Defendants' misrepresentations about opioid abuse and addiction risk were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions, but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. Defendants have made a concerted effort to reach GPs through continuing medical education programs ("CMEs"), office visits, and literature specifically aimed at them, and most opioids are prescribed by primary care physicians like GPs.[33]

88. Defendants organized CMEs for GPs on prescribing opioids to chronic pain patients, but provided no guidance on recognizing opioid abuse or weaning patients off opioids. Since GPs lack specialized training in opioid treatment and are especially reliant on CMEs to equip them to manage patients on opioids, this critical learning gap makes it even less likely that, once on opioids, chronic pain patients will have the chance to get off them.

(3) Deflecting attention to "undertreated" pain.

[33] Wolters Kluwer Health, *Sharp rise in opioid drugs prescribed for non-cancer pain*, Science Daily (Sept. 16, 2013), available at http://www.sciencedaily.com/releases/2013/09/130916091218.htm.

89. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. They claimed that purportedly overblown worries about addiction caused pain to be under-treated and opioids to be over-regulated and under-prescribed. One APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, stated that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include … misconceptions about opioid addiction." The Purdue Guide further alleged that resulting regulatory constraints (like the FDA's recently mandated prescriber education program, or REMS ("Risk Evaluation and Mitigation Strategies") have a "chilling effect" on prescribing and that abuse of opioids injured and "jeopardize[d] effective pain management by impeding patient access to opioids."

90. [redacted]

91. A Purdue website called *In the Face of Pain* complained, under the heading of "Protecting Access," that, through at least mid-2013, policy governing the prescribing of opioids was "at odds with" best medical practices by "unduly restricting the amounts that can be prescribed and dispensed;" "restricting access to patients with pain who also have a history of substance abuse;" and "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe."[34] This unsupported and untrue

[34] *See In the Face of Pain Fact Sheet: Providing Access to Pain Treatment*, Purdue Pharma L.P. (2013), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf

rhetoric aimed to portray doctors who did not prescribe opioids as uncaring, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

(4) Physical dependence vs. addiction.

92. In an effort to underplay the risk and impact of addiction, Defendants frequently claim that while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed by gradually tapering patients' dosage to avoid the adverse effects of withdrawal.

93. For example, in the April 2, 2010 version of its OxyContin label, Purdue states: "**Cessation of Therapy** When the patient no longer requires therapy with OxyContin, taper the dose gradually to prevent signs and symptoms of withdrawal in the physically-dependent patient." The APF *Policymaker's Guide* (2011) funded by Purdue states: "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation."[35] [redacted].

94. Defendants' so-called guidance overstates the ease of withdrawing from long term use of opioids and the adverse effects that accompany their discontinuance. Withdrawal from opioids after long-term use can trigger severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms. The dependence on opioids can be so severe that withdrawal symptoms may persist for months, or even years, after a complete withdrawal from opioids.

95. Defendants also fail to disclose that long-term opioid use often causes psychological, as well as physical, dependence. Addiction is not a switch that is either off or on. Indeed, as the most recent, authoritative Diagnostic and Statistical Manual of Mental Disorders

[35] *A Policymaker's Guide to Understanding Pain & Its Mgmt.*, Am. Pain Found., Oct. 2011 at 31.

("DSM-V") acknowledges, there is a spectrum of disorders that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on that spectrum. [36]

96. This is certainly true of opioids. Anxiety over ending opioid use can trigger cravings for opioids, even after a patient is no longer physically dependent and despite the fact that he or she is not deriving benefits from the treatment. As Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, explains, opioids "hijack[] the brain's reward system," convincing users that "the drug is needed to stay alive."[37] Even absent physical dependence, a patient's fear of the unpleasant effects of discontinuing opioids can cause patients to seek the drugs.[38]

97. Thus, ending opioid therapy is not, as Defendants claim, "simply" a matter of gradually lowering a patient's dosage over time. In fact, one of the significant risks in beginning chronic opioid therapy is that, once patients become physically dependent, it will be difficult for them to ever stop using opioids. According to one study, more than half of patients who continuously use opioids for more than 90 days remain on opioids after more than five years.[39] Most patients who become physically dependent after long term use will require opioid maintenance (through methadone or buprenorphine) for years or decades. Defendants fail to disclose this significant risk to doctors and patients.

98. A publication in Purdue's current catalog of publications for providers, *Providing Relief, Preventing Abuse*, cautions against the "common error" of confusing physical dependence

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[36] For that reason, references to "addiction" in this Complaint refer to this spectrum of substance abuse disorders.

[37] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Register (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

[38] Jane C. Ballantyne & Cathy Stannard, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids*, 21(5) Pain: Clinical Updates, 1-7 (Dec. 2013).

[39] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) Journal of Gen. Internal Med., 1450-1457 (Dec. 2011).

with addiction. It analogizes physical dependence on opioids to physical dependence on antihypertensives (blood pressure medicine) or decongestants.

99. This analogy has no basis in fact. With non-addictive drugs, like blood pressure medicine, patients may experience withdrawal symptoms, but they are rarely difficult to get over, and there is no craving for the drug. However, with long-term use of opioids, even in the absence of a formal diagnosis of addiction, patients often crave the drug long after they have discontinued use. Patients on opioids long-term will often experience symptoms that arguably may not qualify as full-blown addiction, but are certainly not mere physical dependence. Defendants' marketing failed to acknowledge the spectrum of substance abuse disorders short of full blown addiction, which also are cause for concern, and created the sense that doctors need only concern themselves with signs of addiction.

100. As with the claimed low incidence of addiction, the misrepresentation that chronic opioid therapy is easy to stop is important to Defendants' fraudulent marketing scheme. Honestly describing the difficulty of removing patients from opioids after long-term use and the complexity of patients' dependence would rebalance the risk-benefit analysis and stoke doctors' and patients' well-grounded concerns that once on opioids, severe physical and psychological dependence would make it extremely difficult for patients to ever stop their use. It might also motivate the general practitioners to whom Defendants generally marketed opioids for long-term use to refer patients requesting opioids to pain management specialists who would not so easily prescribe them. Defendants also gave GPs a false sense of confidence that they could identify addiction, distinct from physical dependence, which, again, allowed them to believe that they could continue to responsibly prescribe opioids. Defendants chose not to tell the truth so that they could sell more drugs.

(5) Pseudoaddiction.

101. Defendants needed a way to explain why so many chronic non-cancer pain patients on opioids seem to be addicted: they ask for drugs by name, they seek refills earlier than

their supplies should have run out, hoard drugs, or self-escalate their doses. Defendants, led by Purdue, managed masterfully to turn these recognized signs of addiction into a way to sell more opioids through the concept of "pseudoaddiction." Pseudoaddiction, which manifested with all of the signs of addiction, was actually the result of insufficient opioids to treat pain, and should be treated with higher or more frequent doses of the drugs. Defendants claimed that rather than addiction treatment, patients who were pseudoaddicts needed more opioids.

102. Purdue discussed pseudoaddiction in a publication called *Providing Relief, Preventing Abuse*, in which it falsely and misleadingly claimed that the concept of pseudoaddiction had "emerged in the literature" "to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." Purdue went even farther, saying that pseudoaddiction is unproblematic and may occur "occasionally even with successful opioid therapy for pain." This gave doctors confidence that signs of addiction might not be cause for concern. It also misled doctors into believing that the proper response to pain that has not been "effectively treated" through opioid prescriptions is *more* opioids. Purdue's unbranded website, Partners Against Pain.com, also hosted a pamphlet in 2005 titled, *Clinical Issues in Opioid Prescribing*, which included a list of conduct including "illicit drug use and deception" as examples of unproblematic pseudoaddiction-related behavior, not problematic addiction.

103. Defendants also managed to work the misleading concept of pseudoaddiction into medical literature. In a 1994 article, Defendant-sponsored KOL Russell Portenoy described common signs of addiction as potential signs of mere *therapeutic dependence* – which he likened to a diabetic's response to insulin – or *pseudoaddiction*.[40] Portenoy claimed that "*Pseudoaddiction* describes a specific phenomenon that has also been observed in the population with cancer pain." But his authority for this statement was limited to a single citation to an article by another KOL and later Purdue executive J. David Haddox.[41] Dr. Haddox's article did

[40] Portenoy, *supra* note 1, at 266-267.

[41] *Id*. at 267.

not concern a population study at all, but rather, simply reported the possible phenomenon in a single cancer (leukemia) patient with pneumonia and chest wall pain.[42]

104. Dr. Portenoy took the deception of pseudoaddiction one step farther, separating from a list of commonly accepted signs of drug addiction those he claimed were "probably less predictive of addiction."[43] Portenoy's "less predictive of addiction" list included:

i. Aggressive complaining about the need for more drugs;

ii. Drug hoarding during periods of reduced symptoms;

iii. Requesting specific drugs;

iv. Openly acquiring similar drugs from other medical sources;

v. Unsanctioned dose escalation or other noncompliance with therapy on one or two occasions;

vi. Unapproved use of the drug to treat other symptoms;

vii. Reporting psychic effects not intended by the clinician; and

viii. Resistance to a change in therapy associated with 'tolerable' adverse effects with expressions of anxiety related to the return of severe symptoms.

105. Portenoy cited no authority for his "less predictive of addiction" conclusion and is not himself a specialist or authority in addiction medicine. Yet his list encouraged doctors to ignore obvious signs of addiction and prescribe more opioids.

106. Similarly, in his book, *Responsible Opioid Prescribing* (2007), which was funded by Defendants Cephalon, and Purdue, and is still distributed in Chicago, Dr. Scott Fishman asserts: "It may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications. But other causes of non-adherence should be considered before a judgment is made." Thus,

[42] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) Pain, 363-366 (Mar. 1989).

[43] Portenoy, *supra* note 1, at 267 Table III.

according to Defendants, even patients at high risk for opioid addiction should be given the benefit of the doubt (and more opioids).

107. Defendants' used identical language to describe pseudoaddiction in their materials, evidence of their common efforts and messages (emphasis added):

Let's Talk Pain **(2009)**	***A Policymaker's Guide*** **(2011)**	***Clinical Issues in Opioid Prescribing*** **(2005)**
funded by Janssen	funded by Purdue	funded by Purdue
"A related term is pseudoaddiction, which refers to patient behaviors that may occur when **pain is under-treated** . . . Pseudoaddiction is **different from true addiction** because such behaviors can be resolved with effective pain management."	"Pseudo-addiction describes patient behaviors that may occur when **pain is undertreated** . . . Pseudo-addiction can be **distinguished from true add[i]ction** in that this behavior ceases when pain is effectively treated."	"Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when **pain is undertreated** . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be **distinguished from true addition** in that the behaviors resolve when the pain is effectively treated."

108. Despite Defendants' claims, pseudoaddiction has no scientific basis; there is no competent study documenting its existence. Based on a single cancer pain case observed by Purdue executive and KOL David Haddox, Defendants have counseled doctors to treat chronic non-cancer pain patients on opioids who seem to be addicted *with more opioids*.

109. KOL Dr. Lynn Webster recommended just this course in his book, *Avoiding Opioid Abuse While Managing Pain* (2007), [redacted]

[redacted]

Dr. Webster advised giving patients more medication when unsure whether a patient is showing signs of addiction or untreated pain; he asserted that pseudoaddiction was the cause *"in most cases and should be the clinician's first response*." Lynn R. Webster, Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007) (emphasis added). Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to

give patients more medication.… It led us down a path that caused harm. It is already something we are debunking as a concept."[44]

(1) Other adverse effects.

110. Defendants also misrepresent the risks of long-term opioid use by describing them as minor and short-term and failing to disclose the most significant risks. Defendants most frequently highlight the risk of constipation, which they advise can be addressed with laxatives or other treatments. The other side effects Defendants typically disclose are drowsiness, nausea and vomiting, mental clouding (sometimes disclosed), and itching, though Defendants promise that these symptoms will go away in a matter of days.

111. Below is a representative example of how Defendants disclose potential side effects from opioid use in unbranded material. This is taken from a 2009 patient education publication distributed by the NIPC and funded by Endo, and which was distributed in Chicago during the last four years:

[44] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee-Wisconsin Journal Sentinel (Feb. 18, 2012), http://www.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.[45] H. W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3(5) The Journal of Pain, 377-384 (Oct. 2002)Nathaniel Katz & Norman A. Mazer, *Impact of opioids on the endocrine system*, 25 The Clinical Journal of Pain, 170-175 (2009).

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

112. Notably absent from this list are far more significant adverse outcomes linked to long-term opioid use, including: hyperalgesia, immunologic and hormonal dysfunction, respiratory depression, apnea, tolerance/loss of analgesic efficacy, endocrinopathies (most notably testosterone depletion, which, among other impacts, may decrease pain tolerance and the effectiveness of opioids),[45] cognitive impairment, dependence, and addiction. These adverse outcomes can result in an increase in falls and fractures in the elderly (which can shorten the lives of elderly patients), overuse, overdose, and death. Defendants also fail to disclose the risk that infants born to pregnant women using opioids will be dependent on opioids as well, suffering a condition called neonatal abstinence syndrome when they painfully withdraw from the drug after birth.[46] In addition, though the labels for opioids contain numerous warnings about use of opioids for patients who have certain conditions, are opioid naïve (new to opioids), or use other drugs, Defendants' marketing materials contain no similar cautions.

[45] H. W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3(5) The Journal of Pain, 377-384 (Oct. 2002)Nathaniel Katz & Norman A. Mazer, *Impact of opioids on the endocrine system*, 25 The Clinical Journal of Pain, 170-175 (2009).

[46] The FDA now requires a boxed warning on all extended release and long acting opioids, cautioning that chronic use of those drugs by pregnant women can result in neonatal opioid withdrawal syndrome ("NOWS"), which may be life-threatening and require specialized care.

113. These omitted adverse outcomes are not, as Defendants claim, fleeting or minor. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic non-cancer pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[47] Defendants were aware of this high drop-out rate as they pushed the FDA to allow them to exclude these patients from clinical trial data, a method of research known as "enriched enrollment," which allowed drug companies to study only those patients whose negative reactions to opioids did not cause them to stop taking them.

114. Janssen's marketing campaign for Nucynta was particularly deceptive in that it promoted Nucynta's "tolerability," which is completely at odds with and misrepresents its serious side effects. In October 2009, Janssen began to run an advertisement in *Medical Economics* that proclaimed: "OPIOID EFFICACY MEETS UNEXPECTED TOLERABILITY," even though the risk of addiction and serious side effects make opioids intolerable for most patients. While the "tolerability" to which Janssen referred was a lack of GI-related side effects (*e.g.*, nausea and vomiting), a reader could only learn this after examining a bar chart representing the study's results. Thus, the all-caps claim of "unexpected tolerability" falsely implied that Nucynta could be taken without severe side effects or consequences.

115. Defendants' misleading treatment of the serious risks of opioid treatment in unbranded materials directly contradicts the disclosures they made on their own labels. The label for Purdue's OxyContin, for example, acknowledges that its use may increase the risk of serious adverse reactions "including respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, or shock[.]" Likewise, the label for Janssen's Duragesic includes the warning that "[r]espiratory depression is the chief hazard of" Duragesic, and it "has a narrow indication and should be prescribed only by healthcare professionals who are knowledgeable in the administration of potent opioids and management of chronic pain." The labels even include warnings for interactions with substances as commonly used as alcohol, as in the Nucynta ER

[47] Meredith Noble et al., *Long-term opioid management for chronic noncancer pain (Review)*, 1 Cochrane Database of Systematic Reviews, (2010).

label, which says that the drug "may be expected to have additive effects when used in conjunction with alcohol . . . [and] respiratory depression, hypotension, and profound sedation, coma or death may result." Yet, upon information and belief, these risks are not highlighted in the educational programs and marketing materials Defendants have sponsored and disseminated; materials that are much more widely read and relied on than the drug labels.

116. The table below (emphasis added) highlights the differences, described above, between how Defendants (in this instance, Janssen) disclosed side effects in unbranded materials and front group materials, versus how they disclosed side effects in their branded advertisements.

Finding Relief: Pain Management for Older Adults (2009)	**Let's Talk Pain Website (2009)**	**Nucynta IR Advertisement (2010)**
[redacted]	[redacted]	branded Janssen advertisement
"At first, the drugs can cause **upset stomach or sleepiness**. These side effects often go away as you get used to the drugs. Some other side effects, such as **constipation**, don't lessen with time. Constipation can be prevented or lessened by taking a laxative on a regular basis."	"The most common side effects of opioids include **constipation, nausea and vomiting, sedation (sleepiness), mental clouding, and itching**. Some people may also experience **dizziness** or difficulty urinating . . . The good news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is likely to persist."	Prescriber information in the ad states: "**Respiratory depression** is the **primary risk** of mu-opioid agonists."

117. In a 2008 warning letter, the FDA recognized that these strategies deceptively represented the side effects of opioids – in that case, Avinza. The FDA complained that one of the company's marketing materials (a file card) lists common adverse effects "including constipation, nausea, and somnolence," but omitted all of the other risks listed in the drug's package insert. According to the FDA, the file card with a page headed "Managing Side Effects"

> creates the misleading impression that the risk information contained in that section is a comprehensive presentation of the risks associated with Avinza therapy and the steps needed to

> address those risks. The fact that the File Card contains no other disclosure of drug risks reinforces this misleading impression. Furthermore, the File Card – in direct contradiction of the [Package Insert] for Avinza – implies that no serious or life-threatening risks (e.g., risk of respiratory depression, overdose, or death) can be caused by Avinza, both by disclosing only 'common adverse events' (e.g., constipation, nausea, and somnolence) and by emphasizing the drug's 'proven safety and tolerability' throughout the piece. Finally, by framing its discussion of common adverse reactions as one of 'managing' them, and by providing no disclosure to the contrary, the File Card misleadingly implies that common adverse reactions associated with the use of Avinza may ordinarily be alleviated or mitigated, and therefore do not pose a risk to patients…. Your minimization of the serious risk profile associated with your drug raises significant public health concerns.

118. In promoting their opioids, Defendants have engaged in the same marketing practices warned against by the FDA – highlighting only minor risks, emphasizing the ability to manage those risks, failing to disclose serious risks, and generally declaring the safety of their drugs. As the FDA made clear, that message is dangerously deceptive. By deliberately understating the risks of opioids, Defendants exposed patients to extremely dangerous adverse effects and deprived doctors and patients of the ability to make informed, appropriate choices about using opioids.

119. Defendants' pattern of understating the risks of chronic opioid therapies marred the CMEs and studies they funded or sponsored and left providers with the impression that opioids were much safer than they are and should be used more frequently. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded article on opioids versus another group who reviewed a non-industry-funded article. The industry-funded article did not mention opioid-related death once; the non-industry-funded article mentioned opioid-related death 26 times. A summary of the study notes that students who read the industry-funded article more frequently cited the impression that opioids were underused in chronic non-cancer pain. Those reading the non-industry-funded article, in reporting their "take-aways," mentioned the risk of death and addiction much more frequently than the other group. Neither group could accurately identify

whether the article they read was industry-funded, making clear the difficulty providers have in screening and accounting for source bias.[48]

3. Misrepresentations regarding superiority.

120. Defendants' deliberate misrepresentation of the risks of opioids is particularly evident when compared to Defendants' description of the risk of over-the-counter nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal and renal risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, but also made their omissions regarding the risks of opioids all the more striking and misleading.

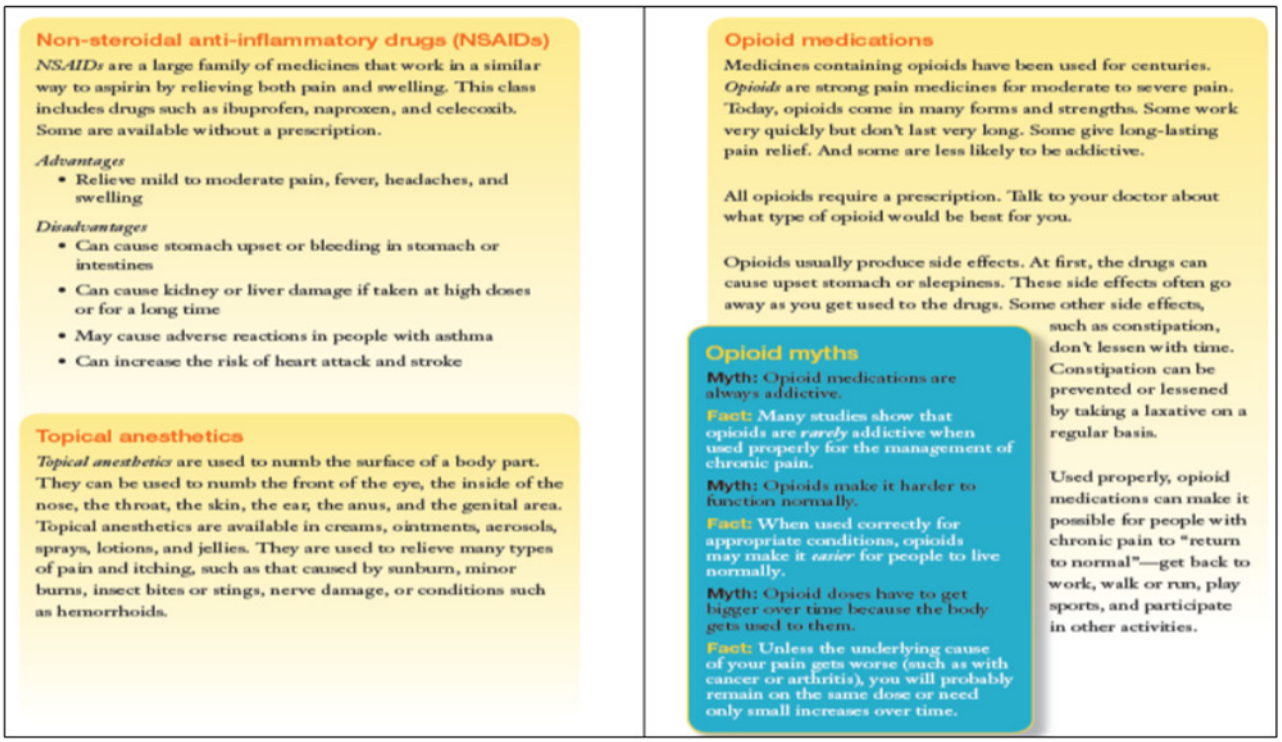
121. In the Cephalon and Purdue-sponsored 2007 APF *Treatment Options*, NSAIDs are described as "life threatening," – a term never used in connection with opioids – and are said to have caused 10,000 to 20,000 deaths each year. The CDC reports that the actual number of deaths even possibly related to the use of NSAIDs in 2008, the most recent year available, is roughly 3,400, and that number includes all gastrointestinal bleeding deaths regardless of cause.[49]

122. [redacted]

[48] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), www.pharmedout.org/Fugh-BermanPrescriptionforconflict6-25-10.pdf

[49] John Fauber, *NSAID Bleeding Risk: Smoke But No Fire*, MedPage Today (May 30, 2012), www.medpagetoday.com/Geriatrics/PainManagement/32971.

123. The Janssen-funded brochure, excerpted below, was also distributed to doctors and patients in Chicago during the relevant time period:



Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs are a large family of medicines that work in a similar way to aspirin by relieving both pain and swelling. This class includes drugs such as ibuprofen, naproxen, and celecoxib. Some are available without a prescription.

Advantages

- Relieve mild to moderate pain, fever, headaches, and swelling

Disadvantages

- Can cause stomach upset or bleeding in stomach or intestines
- Can cause kidney or liver damage if taken at high doses or for a long time
- May cause adverse reactions in people with asthma
- Can increase the risk of heart attack and stroke

Topical anesthetics

Topical anesthetics are used to numb the surface of a body part. They can be used to numb the front of the eye, the inside of the nose, the throat, the skin, the ear, the anus, and the genital area. Topical anesthetics are available in creams, ointments, aerosols, sprays, lotions, and jellies. They are used to relieve many types of pain and itching, such as that caused by sunburn, minor burns, insect bites or stings, nerve damage, or conditions such as hemorrhoids.

Opioid medications

Medicines containing opioids have been used for centuries. *Opioids* are strong pain medicines for moderate to severe pain. Today, opioids come in many forms and strengths. Some work very quickly but don't last very long. Some give long-lasting pain relief. And some are less likely to be addictive.

All opioids require a prescription. Talk to your doctor about what type of opioid would be best for you.

Opioids usually produce side effects. At first, the drugs can cause upset stomach or sleepiness. These side effects often go away as you get used to the drugs. Some other side effects, such as constipation, don't lessen with time. Constipation can be prevented or lessened by taking a laxative on a regular basis.

Used properly, opioid medications can make it possible for people with chronic pain to "return to normal"—get back to work, walk or run, play sports, and participate in other activities.

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

1 - *Finding Relief: Pain Management for Older Adults*, [redacted] by Janssen (2009)

The disclosed risks of NSAIDs include bleeding in the stomach or intestine, kidney or liver damage, and an increased risk of heart attack and stroke. In contrast, the side effects of opioids include an upset stomach, sleepiness, and constipation, though even these side effects often go away or can be managed. [redacted]

124. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.[50]

[50] Mark Olfson et al., *Nat'l Trends in the office-based prescription of schedule II opioids*, 74(9) The Journal of Clinical Psychiatry, 932-939 (Sept. 2013).

D. Defendants, Directly and Through Their Agents and Front Organizations, Made and Caused Their Misrepresentations to Be Made and Broadly Disseminated

125. Defendants have polluted virtually every resource for information on the use of opioids to treat chronic non-cancer pain and have created a deceptively solid foundation of core materials, cited and relied upon by others, to minimize the risks and overstate the benefits of using opioids to treat chronic non-cancer pain. Both directly and indirectly – through doctors, medical education courses, seemingly independent patient advocacy groups, and professional societies like AAPM. Defendants have ensured that their messages reach and expand the market for opioids. [redacted] Defendants have identified, encouraged, and compensated high profile KOLs to give talks and advice and author books and articles. Defendants' KOLs offer and serve on the program committees that choose CMEs, and develop and promote treatment guidelines that promote chronic opioid therapy. Many of these groups and KOLs may have been misled by Defendants in the same manner as general practitioners and family doctors.

126. Directly and through public relations firms they hire, and advocacy groups and professional societies they finance and influence, Defendants have funded, drafted, edited, approved, published, and distributed websites, books, patient education brochures, videos, and other materials that carry their misrepresentations to targeted groups of doctors (such as family doctors), and patients – particularly veterans and the elderly. Defendants carry out their fraudulent promotions both individually and in concert with other industry front groups and each other, and make and disseminate these misrepresentations throughout the City.

1. Method 1: Key opinion leaders ("KOLs")

127. Defendants routinely rely on a small circle of doctors to promote the use of opioids for the treatment of chronic non-cancer pain. These doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research in order to support the broad use of opioid therapy for chronic non-cancer pain. Known by industry shorthand as "KOLs," or key opinion leaders, they have written, consulted on,

edited, and lent their names to books and articles and given speeches and CMEs supportive of chronic opioid therapy. They served on committees that developed treatment guidelines that, even while acknowledging the lack of evidence for their positions, strongly encourage the use of opioids to treat chronic non-cancer pain.

128. [redacted]

129. Defendants' KOLs have served on the boards of the advocacy groups and professional societies that develop and offer CMEs and publish patient education materials on opioids.

130. What Defendants and the KOLs rarely disclose is the substantial sums of money Defendants have paid to the KOLs for consulting and speaking arrangements and to serve on various panels and boards; as well as through purported "research grants." Some KOLs have even gone on to become direct employees and executives of Defendants. Dr. Haddox, for example, was a KOL who, as a physician in private practice, promoted widespread opioid use for chronic non-cancer pain. He was a paid speaker and consultant for Purdue, then became a Purdue senior manager.

131. While some KOLs may initially have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected and funded doctors whose public positions were unequivocal and supportive of using opioids to treat

chronic non-cancer pain.[51] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

132. The KOLs' association with Defendants provided not only money, but also prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community. Upon information and belief, using these KOLs is a central part of Defendants' marketing plans and critical to persuading regulators and doctors – who rely heavily and more uncritically on their peers – that the benefits of chronic opioid therapy outweigh its risks. [redacted]

133. Dr. Russell Portenoy, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and co-opted to further their marketing campaign. With Defendants' support, Dr. Portenoy was dubbed the "King of Pain" by TIME MAGAZINE. He co-authored *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases (1986)*, which asserted, based solely on 38 cases, that chronic opioid therapy was a safe and effective treatment for patients with intractable non-malignant pain.

134. Dr. Portenoy, thus, helped to open the door for the use of opioids to treat chronic non-cancer pain. He served on the American Pain Society/American Academy of Pain Medicine Guidelines Committee, which endorsed the use of opioids to treat chronic non-cancer pain, and the FDA Anesthetic and Life Support Drugs Advisory Committee, one of a host of FDA

[51] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used key opinion leaders in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.[52] Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN Health (Dec. 20, 2013), http://www.cnn.com/2013/12/20/health/pain-pillar/.

advisory committees that serve to provide expertise and technical assistance to assist the FDA decision-making. While he held these positions, he also was receiving research support, consulting fees, or honoraria from Defendants Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

135. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research. He is a Senior Editor of the *Pain Medicine* Journal, which published numerous articles supportive of chronic opioid therapy. He was President, and is a current board member, of AAPM, a Chicago-based front group that ardently supported chronic opioid therapy. Dr. Webster is the author of numerous CME programs, sponsored by Defendants, which contained virtually all of Defendants' misrepresentations described above. At the same time, Dr. Webster was receiving significant funding (including nearly $2 million from Cephalon).

136. Dr. Webster has been under investigation by the U.S. Drug Enforcement Administration, which raided Dr. Webster's clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a screening tool that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids.[52]

137. In a blow to Defendants' marketing campaign, Drs. Portenoy and Webster recently acknowledged shortcomings in their pro-opioid positions. Dr. Webster has admitted that the concept of pseudoaddiction – taking patients at their word and assuming they are not addicts, but just need more pain relief "–became too much of an excuse to give patients more medication . . . It is already something we are debunking as a concept."[53] Dr. Portenoy has admitted that he gave "innumerable lectures in the late 1980s and '90s" in which he asserted that

[52] Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN Health (Dec. 20, 2013), http://www.cnn.com/2013/12/20/health/pain-pillar/.

[53] Ed Silverman, *Opioids & An Overdue Senate Probe: Kolodny Explains*, Pharmalot.com (May 14, 2012), http://www.pharmalot.com/2012/05/opioids-an-overdue-senate-probe-kolodny-explains/.

fewer than 1% of patients would become addicted to opioids that "weren't true." Because the primary goal was to "destigmatize" opioids, he said, "we often left evidence behind." Dr. Portenoy also conceded that "data about the effectiveness of opioids does not exist."[54]

2. Method 2: Co-opting of chronic pain advocacy and research groups to promote opioid use.

138. A key component of Defendants' plans to promote the long-term use of opioids was co-opting pain management organizations and societies and pain patient advocacy groups. Taking a page from the tobacco industry, which had created and used front groups to proclaim tobacco was not harmful, Defendants harnessed and warped existing organizations to disseminate their deceptive messages with the expectation that these messages would circulate among and influence the conduct of prescribing physicians and other members of the medical community. These front organizations appeared to be legitimate scientific and patient advocacy organizations (and perhaps started out as such) and publicized seemingly scientific, balanced, and accurate information on opioid use. In fact, the information was false and misleading and paid for and encouraged by Defendants for the purpose of creating a vast market for the use of opioids for chronic non-cancer pain.

139. The role of these organizations in promoting opioid use and their ties to opioid makers was highlighted when, on May 8, 2012, Senators Grassley and Baucus wrote to a half-dozen of these organizations:

> There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic [of opioid use and abuse] by promoting misleading information about the drugs' safety and effectiveness. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Academy of Pain Medicine, the Federation of State

[54] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), http://online.wsj.com/news/articles/SB10001424127887324478304578173342657044604

> Medical Boards, the University of Wisconsin Pain and Policy Study Group, and the Joint Commission.
>
> In a *ProPublica* story published in the *Washington Post*, the watchdog organization examined the American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry."[55] *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers play down the risks associated with opioids and exaggerate their benefits. Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research.
>
> According to the *Milwaukee Journal Sentinel/MedPage Today*, a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers … helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient litigators, position statements, books and doctor education courses."[56]

140. These front groups, aided by millions of dollars in grants from Defendants and assistance from public relations firms hired by Defendants, spread the misrepresentations central to Defendants' fraudulent promotion of opioids. Indeed, Defendants influenced, if not outright controlled, the messages disseminated by many of these front groups.

a. American Pain Foundation.

141. The most prominent of Defendants' front groups was the American Pain Foundation ("APF"), which received [redacted] in funding from Defendants from 2007 until it closed its doors in May 2012. [redacted]

142. APF issued education guides for patients, reporters, and policymakers that promoted the benefits of opioids for chronic non-cancer pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for

[55] Charles Ornstein & Tracy Webber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), http://www.propublica.org/article/the-champion-of-painkillers.

[56] John Fauber, Follow *the Money: Pain, Policy, and Profit*, Milwaukee Journal Sentinel/MedPage Today (Feb. 19, 2012), http://www.medpagetoday.com/Neurology/PainManagement/31256.

returning veterans, described in greater detail below; promotion of opioids to treat veterans has contributed to high rates of addiction among returning soldiers. APF engaged in a significant multimedia campaign – through radio, television and the web – to educate patients about their "right" to pain treatment – namely opioids. KOLs funded by Defendants, including Drs. Perry Fine, Scott Fishman and Kathleen Foley, also served on APF's Board of Directors.

143. In 2009 and 2010, [redacted] of APF's operating budget came from industry sources. Including industry grants for specific projects, in 2009, APF received [redacted] from industry sources out of total income of [redacted]; its budget for 2010 projected receipts of [redacted] from drug companies, out of total income of [redacted]. [redacted]

144. But the control was even more direct than the money. [redacted]

145. [redacted] opioid "tool-kit" for the National Initiative on Pain Control [redacted] included two of Defendants' key misrepresentations:

- After starting opioid therapy, you may see the following positive improvements: - Your pain level may decrease[;] -Your level of function should improve: you may find you

are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse[;] - Your sleep may improve.

- People who take opioids as prescribed usually do not become addicted.

146. At a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the oxycontin criminal settlement," APF aggressively defended Purdue, repeatedly denying that patients prescribed opioids abuse or become addicted to the drugs. APF's board chairman, Dr. James Campbell, described addiction as a "rare problem" for chronic non-cancer pain patients and asserted that "the scientific evidence suggests that addiction to opioids by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of oxycontin and the abuse and diversion of the drug."

147. Despite APF's unequivocal pro-opioid positions, [redacted]

148. On May 8, 2012, Senators Grassley and Baucus wrote the Chairman of APF seeking information about the source of its funding and asked for a response by June 8, 2012. APF shuttered its offices and dissolved before that deadline.

b. American Academy of Pain Medicine.

149. The American Academy of Pain Medicine with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted

[redacted]

medical education programs critical to Defendants' deceptive marketing of chronic opioid therapy. [redacted] AAPM created and maintained a corporate relations council, whose members paid $25,000 a year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with the AAPM's marquee event – its annual meeting in Palm Springs. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

150. Additionally, AAPM retained pro-opioid KOLs to serve on its board of directors, and advisory committees; further, allowing the organization to be used to promulgate the pro-opioid misrepresentations being pushed by the opioid manufacturers. Notably, one of AAPM's recent past presidents, Dr. Lynn Webster, was appointed to the position while he was being investigated by the DEA as a result of more than 20 deaths of chronic pain patients of Dr. Webster's clinic, who were prescribed and were taking prescription opioids. Another outspoken pro-opioid KOL, Dr. Russell Portenoy, also served as a recent past president of AAPM.

151. The AAPM and the American Pain Society issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Defendant Purdue; three years later, he became Vice President for Health Policy at Purdue. AAPM and the American Pain Society issued guidelines in 2009 and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the guidelines, including KOL Dr. Portenoy, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Upon information and belief, the 1997 consensus statement remained on AAPM's website until 2011, and was taken down only after a doctor complained.

3. Method 3: Treatment guidelines.

152. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts in, nor trained in, the treatment of chronic non-cancer pain. Treatment guidelines used in making treatment decisions are cited throughout the scientific literature and are referenced by third-party payers in determining whether they should cover treatments for specific indications.

153. As noted above, in 2009 AAPM, together with the American Pain Society ("APS"), issued their *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain*. The Guidelines represented a marked departure from previous guidelines for the promotion of opioids. The APS/AAPM guidelines promote opioids as "safe and effective" for treating chronic non-cancer pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients with and without past abuse histories. One member of the panel, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and the founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions by Defendants to the sponsoring organizations and committee members. These guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but the body of scientific evidence on opioids; the APS/AAPM guidelines have been cited 732 times in academic literature that was disseminated in Chicago during the relevant time period, are still available on the internet, and were reprinted in the *Journal of Pain*.

154. In 2009, the American Geriatric Society ("AGS") revised its guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines [redacted] included the following recommendations:

- "All patients with moderate to severe pain … should be considered for opioid therapy (low quality of evidence, strong recommendation)."
- "[Th]e risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."

These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence.

155. According to one news report, AGS received $344,000 in funding from opioid makers since 2009.[58] Five of 10 of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock.[59]

156. In contrast, treatment guidelines that did not receive industry backing are much more reserved and endorse chronic opioid therapy only in narrow circumstances. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians, included a disclaimer that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." The American Society of Interventional Pain Physicians Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and

[58] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee Journal Sentinel/MedPage Today (May 30, 2012), http://www.medpagetoday.com/Geriatrics/PainManagement/32967.

[59] The Institute of Medicine recommends that, to ensure an unbiased result, that fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

political propaganda under the guise of improving the treatment of chronic pain." They recommend long-acting opioids in high doses only "in specific circumstances with severe intractable pain … with continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."

157. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommended against "routine use of opioids for treatment of chronic pain patients," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.

158. Industry supported guidelines, in contrast, separate the strength of the recommendation from the strength of evidence supporting the recommendation. For instance, most of the "strong" recommendations of the APS/AAPM guidelines are backed by only what the guidelines describes as weak evidence. Further, the guidelines Defendants supported fail to adequately take into account the potential adverse effects and specific label warnings that a physician should take into consideration in deciding on a treatment for any medical condition. As a result, they present a distorted picture of treatment options.

159. The separation of recommendations from the strength of supporting evidence proved useful for drug companies in promoting their opioids individually. [redacted] Upon information and belief, the guidelines were widely referenced and promoted by the drug companies and their KOLs and front groups without disclosing the acknowledged lack of evidence to support them. This dangerously misrepresented to doctors the credibility and applicability of the pro-opioid recommendations.

4. Method 4: Continuing medical education.

160. The millions of doctors and other health care professionals[60] who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. Defendants have sponsored thousands of CME programs that promote chronic opioid therapy and support and disseminate the deceptive and biased messages described in this Complaint. Upon information and belief, Defendants' grant making to fund and sponsor CMEs has been influenced by their marketing strategies and harnessed to the goal of increasing opioid sales. Upon information and belief, Defendants are more than passive funders of these programs, which reached tens of thousands of doctors; they have influenced, if not outright controlled, the messages on topics and in the fields of practice Defendants targeted.

161. The American Medical Association has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[61]

162. Defendants have long-standing relationships with the professional associations, advocacy organizations, presenters, and CME development companies that select and develop opioid-related CMEs. These other organizations have depended upon Defendants' financial support for their activities and, in some cases, their very existence. It stands to reason that each of these organizations and the individuals running them know and believe that future financial support from Defendants depends upon producing programs that support the use of Defendants' products.

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[60] Lisa M. Schwartz & Steven Woloshin, *Medical Communication Companies and Continuing Medical Education: Clouding the Sunshine*, 310(23) The Journal of the Am. Med. Ass'n 2507, 2507 (Dec. 18, 2013).

[61] *Opinion 9.0115 – Financial Relationships with Indus. in CME*, Am. Med. Ass'n (Nov. 2011), http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion90115.page.

163. Defendants are able to influence CMEs because they fund: (1) the KOLs who serve on the program committees of the professional societies that select the presentations and speakers and promote the views on which the presentations rely; (2) the KOLs who serve as speakers for the CMEs; and (3) the professional societies that host the conferences at which the presentations are given. Upon information and belief, many of these programs focus exclusively on prescribing opioids, and do not fairly present reasonable alternative treatments (except to discount them), nor do they fairly present (or present at all) the risks or benefits of chronic opioid therapy, nor how to take patients off opioids, once prescribed.

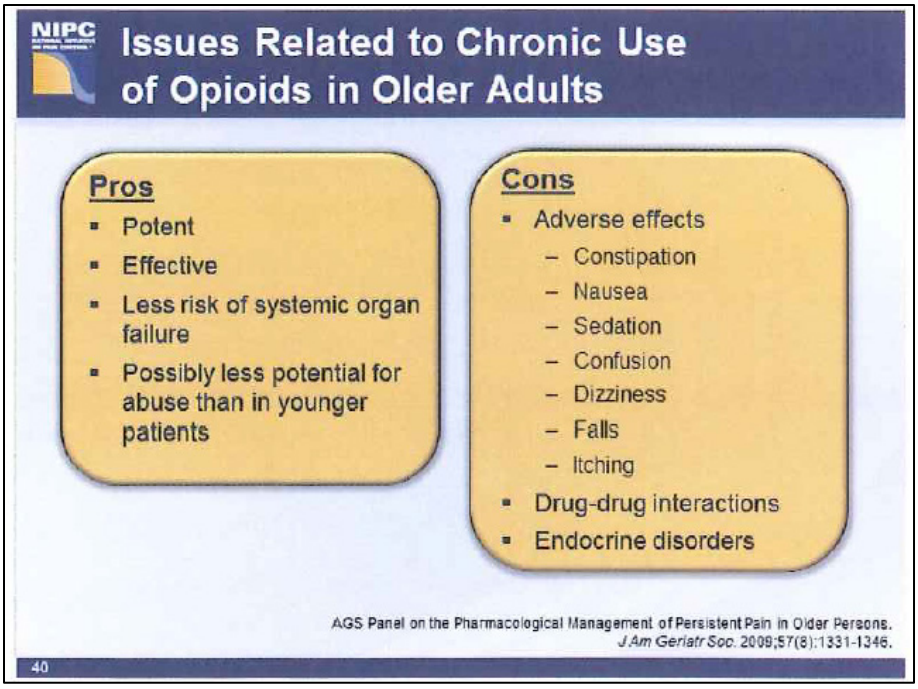
164. Defendants' sales representatives participated in conferences at which the CMEs were presented, encouraged doctors to attend the programs, and held auxiliary events that reinforced and amplified the distorted messaging of the CMEs. The CMEs themselves, however, buttressed by printed disclaimers by Defendants, were marketed to appear evidence-based and unbiased. In fact, like KOLs, the CMEs are particularly effective for disseminating Defendants' messages because doctors rely on these peer-led professional events to deepen their understanding of clinical issues.

165. *Path of the Patient, Managing Chronic Pain in Younger Adult at Risk for Abuse*, a CME program sponsored in part by Purdue and edited by KOL Dr. Perry Fine, provides one example of Defendants' use of CMEs to spread deceptive messages supportive of chronic opioid therapy. *Path of the Patient* aimed to educate primary care doctors about managing chronic non-cancer pain with opioids. The presentation is devoted entirely to opioid prescribing and, despite its title, presents *no other* potential treatments. Far from a therapy of last resort, as conventional medical thought advised, *Path of the Patient* promotes opioid therapy as the only solution, even for common chronic non-cancer pain issues such as back pain. This CME was available on-line for Chicago physicians, and others, to view during the relevant time period.

166. In a role play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills a day as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of

drug and alcohol abuse. Even given these facts, an authoritative narrator notes that, because of a condition known as pseudoaddiction, the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long-acting opioid.

167. An Endo-sponsored CME put on by the APF's National Initiative for Pain Control, *Persistent Pain in the Older Adult*, similarly reprises several of Defendants' misrepresentations. The program was first made available on-line, including to Chicago physicians, and others, in 2011 and continued to be available during the relevant time period. The CME describes fear of addiction, safe use, and drug-drug interactions – all factors relating to addiction, abuse, and overdose – as the most significant barriers to treating "persistent" or chronic non-cancer pain in the elderly. The presentation counsels that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). Citing the AGS's treatment guidelines as its sole support, the CME describes the "chronic use of opioids in older adults" as "effective" and notes "possibly less potential for abuse than in younger patients." Its listed adverse outcomes simply omit addiction, overdose, respiratory depression, or death, among others, and the slides note that tolerance to opioids more mild side effects (such as dizziness or nausea) "develops within days to weeks." The CME never discloses the heightened risks opioids pose to elderly patients (see below).



168. Dozens of CMEs that were available during the relevant time period and continue to be available to doctors in Chicago during the relevant time period also promoted the false concepts that opioids improve quality of life and physical function, that the risk of addiction to opioids is low and that doctors can identify and manage patients at higher risk of addiction. The programs train doctors to use specific risk training tools without disclosing that the tools are unproven or the lack of evidence that high-risk – or any – patients can take opioids long-term without becoming addicted.

5. Method 5: Scientific articles.

169. Defendants rely on misleading and deceptive citation of scientific articles to overstate the benefits of chronic opioid therapy and minimize its serious risks and fail to disclose contrary evidence. For instance, the Purdue-funded *Policymaker's Guide* (2011) makes the particularly callous representation that less than 1% of children prescribed opioids will become addicted. In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain. The purpose of the *Guide* was to support opioid therapy generally; it was not focused on or restricted to cancer pain patients — the only population addressed in Dr.

Foley's article, which also did not reference pediatric cancer patients or include any statistics on addiction rates. Purdue funded and distributed the Guide with this misleading citation, knowing that there was no evidence to support the general assertion that children will not become addicted to opioids, even when taken long-term. The Guide was disseminated in Chicago within the relevant time period.

170. Similarly, a 2003 scientific study funded by Purdue and co-authored by a Purdue employee concluded that OxyContin is "effective and safe for the management of [chronic diabetes-related pain] and improves QOL [quality of life]." The study asserts that there is "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse." The authors cite a single article by Porter and Jick, *Addiction Rare in Patients Treated with Narcotics*, published in the prestigious NEW ENGLAND JOURNAL OF MEDICINE. What the authors fail to disclose is that the "evidence" is actually a letter to the editor, not a peer reviewed article. Moreover, the letter describes not a study but a chart review of hospitalized patients; if medical charts failed to note that the patients exhibited documented signs of addiction while on opioids, the authors concluded that they were not addicted. Not only did the study not support the authors' assertion, but the authors' misleading citation of it created a false impression of its reliability. The Porter and Jick letter and the 2003 Purdue study have been cited 819 and 455 times, respectively, in the medical literature since 2008.

171. Practicing doctors, particularly the busy family doctors and general practitioners targeted by Defendants, do not have the time to look behind seemingly authoritative sources, particularly in scientific literature. They do – and must be able to – rely on citations to scientific literature, a fact that Defendants use to their advantage. Moreover, the misleading use of studies to give them weight or meaning they do not have is like a virus; once embedded in the literature, it takes on a life of its own. Studies that assert addiction is rare, relying either on the Foley or Porter-Jick analyses, themselves are cited for the proposition. Thus, with a few key manipulations and deceptive citations, Defendants were able to seed a scientific consensus supportive of chronic opioid therapy.

6. Method 6: Patient education.

172. Defendants reach chronic non-cancer pain patients through written publications, websites, and videos designed to present the purported "facts" about opioids in a simple, user-friendly manner. As Defendants know, these materials are accessed by both patients doing their own research and doctors, who read them when distributing them to patients. The materials Defendants produced concerning opioids include numerous fraudulent representations, overstate the benefits of chronic opioid therapy, and fail to fully disclose its risks, particularly the risks of addiction.

173. [redacted] The pamphlet, *Finding Relief: Pain Management for Older Adults* (2009, also sponsored by AGS, and American Academy of Pain Medicine) is unbranded, [redacted]

174. *Finding Relief* describes opioids as "rarely addicting when used properly for the management of chronic pain" and assures that "unless the underlying cause of your pain gets worse … you will probably remain on the same dose or only need small increases over time." As described above, these contentions are wholly lacking in scientific or clinical support. [redacted]

175. Defendants created campaigns – including literature, websites, community groups, and programs – related to chronic non-cancer pain from illnesses such as lower back pain, shingles, migraines, osteoarthritis, phantom limb pain, fibromyalgia, and multiple sclerosis. These conditions affect significant numbers of people, who have formed affinity groups and on-line communities for support in seeking to address conditions that produce persistent pain and may necessitate long-term treatment. Defendants used this community-building to promote the use of opioids in the treatment of these conditions, despite the fact that there was little or no

scientific evidence supporting the use of opioids for these conditions, and little or no evidence supporting or even suggesting that the use of opioids for these conditions would provide more benefit from pain relief than harm from the many known and significant opioid treatment risks. None of these conditions reflect indications approved to appear on Defendants' drug labels, supporting the inference that Defendants did not have evidence to obtain such approval.

176. In addition to their general marketing efforts, Defendants made special efforts to market to two particularly vulnerable patient groups: the elderly and veterans. While obvious markets for chronic non-cancer pain medications, each of these patient populations has risk factors that make long-term opioid use particularly dangerous.

a. Elderly patients

177. Elderly patients taking opioids have been found to suffer elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels, occurs more frequently in elderly patients.[62] A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[63] Defendants' targeted marketing to the elderly and the absence of cautionary language in its promotional materials flies in the face of scientific evidence and even their own labels and creates a heightened risk of serious injury.

178. In their effort to reach elderly patients, who experience pain associated with arthritis and other aging-related conditions, [redacted] education materials focused on elderly patients. *Finding Relief: Pain Management for Older Adults*, a 2009 publication sponsored by Janssen, as noted above, repeated the same unsubstantiated, deceptive statements that opioids are

[62] Kathleen W. Saunders et al., *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, 25(4) Journal of Gen. Internal Med., 310-315 (Apr. 2010).

[63] Daniel H. Solomon et al., *The Comparative Safety of Analgesics in Older Adults with Arthritis*, 170(22) Archives of Internal Med., 1968-1976 (Dec. 13, 2010).

"rarely addictive" and increase patients' function, allowing them to get back to work or participate in recreational activities.

179. Upon information and belief, other Defendants also focused outreach efforts on the elderly. [redacted].

180. Defendants also promoted the notion – also without adequate scientific foundation – that the elderly are particularly unlikely to become addicted to opioids. The AGS's 2009 Guidelines, for example, described addiction rates as "exceedingly low in older patients with no current or past history of substance abuse." Yet, a 2010 study that examined overdoses among long-term opioid users found that the largest number of patients among those with serious overdoses were 65 or older.[64]

181. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

b. Veterans

182. Veterans, too, are suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed prescription drug abuse among military personnel doubled from 2002 to 2005 and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they did in 2001.[65] Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days.[66] Although, upon information and belief, many of these veterans

[64] Kate M. Dunn et al., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Annals of Internal Med. 85, 89 (Jan. 19, 2010).

[65] Bill Briggs, *VA Docs Defied Opiate Rules in Treating Vets, Audit Finds*, NBC News (May 15, 2014), http://www.nbcnews.com/storyline/va-hospital-scandal/va-docs-defied-opiate-rules-treating-vets-audit-finds-n106461.

[66] American-Statesman Investigative Team, *Prescription drug abuse, overdoses haunt veterans seeking relief from physical, mental pain*, Austin American-Statesman (Sept. 29, 2012),

are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving Veterans' Administration ("VA") services nationally in a single year (2005), 1,013 had died of accidental drug overdoses – double the rate of the civilian population. VA facilities outside of Chicago, which, upon information and belief, serve Chicago residents who are veterans, saw dramatic increases in their rates of prescribing opioids.

183. Opioids are particularly dangerous to veterans. According to a study published last year in the Journal of American Medicine, veterans returning from Iraq and Afghanistan prescribed opioids have higher incidence of adverse clinical outcomes, like overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.[67] Yet, according to a Veterans Affairs Office of Inspector General Report, 92.6% of veterans chronically prescribed opioid drugs were also prescribed benzodiazepines.[68] Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and failed to disclose in their promotional materials the known, serious risks opioids posed to them.

184. Defendants have targeted veterans with fraudulent and unproven representations. As early as 2001, a Purdue promotional plan described spending hundreds of thousands of dollars to target the Veterans Administration and admitted that it was using "education" for what was actually marketing.[69] "Corporate initiatives and partnering efforts were very successful with

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http://www.statesman.com/news/news/prescription-drug-abuse-overdoses-haunt-veterans/nSPLW/

[67] Karen H. Seal et al., *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan*, 307(9) The Journal of the Am. Med. Ass'n, 940-947 (Mar. 7, 2012).

[68] Briggs, *supra* note 65.

[69] American-Statesman Investigative Team, *Critics say pharmaceutical firms spurred the increase in prescriptions for narcotic painkillers,* Austin American-Statesman (Sept. 29, 2012),

the Veterans Administration. In addition to building sales for OxyContin tablets, it also positioned Purdue as the leader in pain management education."[70]

185. *Exit Wounds*, a 2009 publication [redacted] promoted as a personal narrative by one veteran writing to others, describes opioids as "under-used" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "*increase* your level of functioning" (emphasis in original) and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The book also asserts that "denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of State Medical Boards." The U.S. Federation of State Medical Boards itself received support from Defendants during the time it created and published its guidelines for prescription of opioids. Upon information and belief, *Exit Wounds* was disseminated in Chicago within the relevant time period.

186. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with anti-anxiety medications taken by a significant number of veterans. [redacted]

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http://www.statesman.com/news/news/local-military/critics-say-firms-spurred-painkiller-prescriptions/nSPNL/

[70] *Id.*

187. The deceptive nature of *Exit Wounds* is made obvious in comparing it to guidance on opioids published by the VA and Department of Defense ("DOD") in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses or using multiple doctors for prescriptions and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death – none of which are disclosed in *Exit Wounds*. *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the DOD, discloses that its review "revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps … include: lack of effectiveness studies on long-term benefits and harms of opioids …; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification …; lack of evidence on the utility of informed consent and opioid management plans …; and treatment of patients with chronic noncancer pain at higher risk for drug abuse or misuse." These disclosures are missing from Defendants' marketing to veterans.

E. Defendants Often Acted Together in Promoting Opioids, Opposing Regulation and Facilitating Supportive Standards to Approve Opioids

188. As laid out above, Defendants supported, assisted, encouraged and/or facilitated the same front groups and KOLs to disseminate the same deceptive messages about the use of opioids to treat chronic non-cancer pain. In fact, the similarity of their messages, language, and even their formatting (*e.g.*, the myth/fact formulation) suggests that Defendants participated in a common scheme to disseminate misleading information about opioids.

189. This inference is supported by Defendants' cooperation in other activities to promote opioids, including successful efforts to set standards for measuring and treating pain, training and regulating doctors, and approving new opioids.

190. Defendants' efforts to shift the paradigm on opioids and pain treatment began soon after their branded opioids were launched. In 2000, the Joint Commission on Accreditation

of Healthcare Organizations ("JCAHO"), in conjunction with the University of Wisconsin Pain and Studies Group, declared that pain was the "5th Vital Sign" and required all healthcare practitioners to make pain assessment and management a priority in daily practice.

191. Upon information and belief, the impetus behind the new pain standard began with June Dahl, then a professor of pharmacology at the University of Wisconsin-Madison. Dr. Dahl approached JCAHO with a proposal and helped identify pain management experts and key organizations to act as advisors to JCAHO, as well as promoters of Pain as the 5th Vital Sign. Those experts and key organizations are many of the same heavily funded KOLs and front groups that ultimately helped bring about the change in attitudes towards opioids and, subsequently, the rise in opioid prescribing. Defendant Purdue was one of two companies that paid for programs across the country to educate hospital physicians and staff about complying with the new pain standards and had exclusive rights to distribute certain education materials to JCAHO members.[71]

192. Once health practitioners were required to consider a patient's pain along with other vitals, the next step was to convince practitioners that all pain must be treated – preferably with opioids. In 2004, the Federation of State Medical Boards revised and updated its Model Policy for the Use of Controlled Substances for the Treatment of Pain. In support of those efforts, noted KOL Dr. Scott Fishman was tapped to author a companion piece, titled *Responsible Opioid Prescribing: A Physician's Guide* (2007)

193. The Guide was sponsored by Defendants Endo, and Purdue and was distributed to state medical boards, healthcare regulatory boards, medical organizations, hospitals and physicians across the country, including in Chicago. [redacted] The *Physician's Guide* contained many of the misrepresentations described above, notably the concept of pseudoaddiction and the claim

[71] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem,* U.S. Gen. Accounting Office (Jan. 22, 2004), www.gao.gov/htext/d04110.html.

that opioids improve function. [redacted].

194. Defendants also worked together to promote opioids through the Pain Care Forum. The Forum is comprised of representatives from opioid manufacturers and distributors (including each of the Defendants); doctors and nurses in the field of pain care; health care professional organizations (*e.g.*, American Academy of Pain Management, American Pain Society, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and the American Chronic Pain Association); and other like-minded organizations (*e.g.*, Federation of State Medical Boards and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants. Upon information and belief, the Pain Care Forum was started, and continues to be run, by Defendant Purdue's in-house lobbyist Burt Rosen, previously in conjunction with APF. [redacted]

195. Upon information and belief, Defendants collaborated on a common campaign to build a market for opioids for chronic non-cancer pain, which they could share. .

F. Defendants Also Acted Individually to Deceptively Promote Their Opioids for Chronic Non-Cancer Pain.

196. In addition to participating in a shared campaign to expand the market for opioids by reaching chronic non-cancer pain patients and conditions, each Defendant acted on its own to deceptively market its specific opioids for chronic non-cancer pain and to capture a larger share of the chronic non-cancer pain market. Separately, in their branded materials and on seemingly independent websites, they each overstated the benefits and understated the risks of their drugs in the various ways described above, often causing the FDA to formally admonish them. On top of this, Cephalon engaged in additional unlawful conduct, marketing its opioid Fentora for unapproved chronic pain uses despite only recently settling a case involving almost identical activities with respect to its predecessor, Actiq. A review of the City's claims also suggests that opioids were prescribed, and potentially marketed, for off-label uses to treat depression. Purdue

also quickly began to violate a consent judgment with the federal government and the State of Illinois by continuing to misrepresent the risks and benefits of OxyContin and its other opioids.

1. Cephalon fraudulently marketed Actiq and Fentora.

197. Cephalon also engaged in a distinctive effort to market its opioids for chronic non-cancer pain despite having labels that specifically limited their use to cancer pain. As a result of its successful marketing efforts, Cephalon reaps significant revenue from selling its opioids for treatment of chronic non-cancer pain. However, neither of its two opioid drugs – Actiq or Fentora – is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction and in order to claim its piece of the broader chronic non-cancer pain market, Cephalon deceptively and unlawfully marketed Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed, causing prescriptions to be written and paid and, grievously, patients to be injured and die.

a. Cephalon launches its fraudulent marketing scheme of Actiq.

198. Cephalon's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate." [72]

199. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain. Actiq is a rapid onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose

[72] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs,* The Wall Street Journal (Nov. 3, 2006), http://online.wsj.com/news/articles/SB116252463810112292.

for patients who are not opioid tolerant, that is, patients who have taken specific dosages of opioids for a week or longer and whose systems have acclimated to the drugs.

200. In 1995, the FDA approved Actiq "**ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." (Emphasis in FDA document.) Because of Actiq's dangers, wider, off-label uses – as the FDA label makes clear – are not permitted:

> Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients."
>
> Actiq is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

(Emphasis in original.) Unlike other drugs, where off-label uses are permitted but cannot be promoted by the drug maker, Actiq is so potent that off-label use to opioid naïve patients is strictly forbidden.

201. Notwithstanding the drug's extreme potency and related dangers and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic non-cancer pain – an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports related injuries, and other conditions not associated with cancer for which it was not approved, appropriate, or safe.

202. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population. But by 2005, Actiq sales reached $412 million, making it Cephalon's second highest selling drug. As a result of Cephalon's deceptive, unlawful marketing, sales exceeded $500 million by 2006.

b. Cephalon fraudulently marketed Actiq's successor drug, Fentora.

203. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, Cephalon purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application (NDA) to the FDA for approval.

204. Like Actiq, Fentora is an extremely powerful opioid. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth. Like Actiq, Fentora is a rapid onset opioid.

205. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already receiving and were tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

206. Fentora's inherent danger is confirmed by the unusually strong and detailed black box warning label – the most serious medication warning required by the FDA. The warning makes clear that, among other things:

> Reports of serious adverse events, including deaths in patients treated with *FENTORA* have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of *FENTORA* for any other fentanyl product may result in fatal overdosing.
>
> *FENTORA* is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
>
> FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients,"
>
> . . .
>
> *FENTORA* is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

(Emphasis in original.)

c. October 1, 2006 – Cephalon launches Fentora and immediately begins deceptive marketing campaign.

207. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it developed for Actiq and simply substituted in Fentora. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably be off-label.

208. Cephalon's marketing of Actiq "primed the market" for Fentora. Cephalon had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally – not breakthrough cancer pain in particular – from Actiq.

209. On February 12, 2007, only five months after the launch, Cephalon CEO Frank Baldino told investors:

> [W]e've been extremely pleased to retain a substantial portion, roughly 75% of the rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.[73]

210. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses. He identified two "major opportunities" – treating breakthrough cancer pain and:

> The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain. . . . .

[73] *See Cephalon Q1 2007 Earnings Call Transcript,* Seeking Alpha (May 1, 2007, 8:48 PM EST), http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript (last visited May 27, 2014).

> We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . Noting that opioids are "widely used in the treatment of . . . non-cancer patients," Roche continued:
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[74]

d. September 2007 – Reports of death and serious side effects lead the FDA to issue a public health warning for Fentora.

211. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora and indicating that "[t]hese deaths occurred as a result of improper patient selection *(e.g.*, use in opioid non-tolerant patients), improper dosing, and/or improper product substitution." The warning did not acknowledge Cephalon's deliberate role in the "improper patient selection."

212. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora only should be prescribed for approved conditions and that dosage guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label use. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, post-operative pain, or pain due to injury, and that it should be given only to

[74] *Id.*

patients who have developed opioid tolerance. The Advisory reiterated that because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.

e. Cephalon sponsored CMEs used to promote the off-label use of Actiq and Fentora – 2007-2008, in spite of the FDA warnings.

213. Cephalon also used the CME programs it sponsored to promote the off-label use of their Actiq and Fentora. In 2007 and 2008, Cephalon sponsored three CMEs available to Chicago physicians that each positioned Actiq and Fentora, and only Actiq and Fentora, as "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs only use the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME would know to prescribe Actiq or Fentora.

214. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Lynn R. Webster and M. Beth Dove. It recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid onset opioid when it cannot. The only examples of rapid onset opioids then on the market are oral transmucosal fentanyl citrate (*i.e.*, Actiq) or fentanyl effervescent buccal tablet (*i.e.*, Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients *and are frequently prescribed to treat [breakthrough pain] in noncancer patients as well*." (Emphasis added.)

215. Similarly, *Breakthrough Pain: Improving Recognition and Management*, offered between March 31, 2008, and March 31, 2009, by Medscape, LLC completely omitted tolerance

limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like the "Optimizing Opioid Treatment" CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, *Opioid-Based Management of Persistent and Breakthrough Pain*, with Dr. Christine A. Miaskowski. They instruct their audience, "Clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommend "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," *i.e.*, Actiq, and "fentanyl buccal tablet," *i.e.*, Fentora, including specifically in patients with chronic non-cancer pain.

216. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines that she served on Cephalon's speakers' bureau. Dr. Fine and Dr. Webster also received funding from Cephalon for consulting services, and upon information and belief, Drs. Fine and Webster continued to receive funding from other opioid manufacturers, too.

f. May 6, 2008 – The FDA rejects Cephalon's request for expanded approval of Fentora.

217. Cephalon filed a supplemental new drug application, ("sNDA"), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. To support its application, Cephalon admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.[75] Cephalon argued for the expanded approval even though, as it acknowledged, "[t]o date, no medication has been systematically evaluated in clinical studies or

[75] *See Fentora (fentanyl buccal tablet) CII: Advisory Comm. Briefing Document,* U.S. F.D.A. Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (Apr. 4, 2008), http://wwvv.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf (last visited May 27, 2014).

approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain." *Id.*

218. The FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.[76] By a vote of 17-3, the relevant Advisory Committee – a panel of outside experts – voted against recommending approval of Cephalon's sNDA for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied Cephalon's application and requested, in light of its already off-label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk Management Program. In December 2008, the FDA followed that up with a supplemental request, asking that the company submit a Risk Evaluation and Mitigation Strategy for Fentora as well.

g. March 26, 2009 – the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned Cephalon about its misleading advertising of Fentora.

219. Undeterred by the rejection of its sNDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade over Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, Cephalon also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not simply those who were opioid tolerant.

220. On March 26, 2009, the DDMAC issued a Warning Letter to Cephalon, telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug. Specifically, the Warning Letter asserted that a direct-to-patient advertisement found on the internet was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is

[76] *See Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System ("AERS") Database*, U.S. F.D.A. Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008)„ http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDA-corepresentations.ppt#289,1 (last visited May 27, 2014).

a candidate for Fentora therapy … when this is not the case." DDMAC emphasized that Fentora's label was limited to cancer patients with breakthrough pain **"who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."** (Emphasis in original.) DDMAC explained that the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original.) DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (Emphasis in original.)

h. Cephalon continues to knowingly, deceptively, and illegally promote Fentora for off-label uses.

221. Cephalon's own market research studies confirm that its Fentora promotions were not focused on the physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

222. Yet Cephalon continued to use its general pain sales force (which numbered over 110 representatives) to promote Fentora to general pain specialists.

223. Cephalon-set sales quotas for its general pain sales force would be unattainable if they did not deceptively promote Fentora off-label. The general pain sales representatives have, from the outset, been required to adhere to call lists that include numerous pain doctors and other physicians who do not, and would not, prescribe Fentora on-label. These same call lists contain few, if any, oncologists.

224. A 2009 PowerPoint presentation by Kathy Roman, Cephalon's Associate Director of Oncology for Strategic Analysis & Planning, reported that only 4% of Fentora prescriptions were written by oncologists. [redacted]

225. Cephalon's conduct in marketing Actiq and Fentora for chronic non-cancer pain, despite their clear (and deadly) risks and unproved benefits, was an extension of, and reaped the benefits of, Cephalon's generally deceptive promotion of opioids for chronic non-cancer pain.

2. Purdue's role in deceptively promoting opioids for treatment of chronic non-cancer pain.

226. Like Cephalon, Purdue also undertook its own separate campaign to deceptively market opioids. Purdue is the maker of OxyContin, which, over time, has been the most used and abused opioid. Today, with one exception, all of the drugs marketed by Purdue are opioids.

a. Purdue's marketing of OxyContin was deceptive from the start.

227. OxyContin was approved by the FDA in 1995 for "management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." Purdue immediately began promoting OxyContin as less addictive than other opioids. The drug's extended-release mechanism, according to Purdue, meant it was less likely to provide a euphoric

high and therefore was less likely to be abused, create addiction, or cause withdrawal. However, Purdue "did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications."[77] When crushed, dissolved in water, or injected, OxyContin's extended-release mechanism could be bypassed to produce a heroin-like high. In fact, OxyContin was more likely than other opioids to be abused and diverted because it had more oxycodone than other non-controlled release opioids (and oxycodone already is twice as potent as morphine).

228. Purdue's marketing persuaded primary care physicians that it was safe to prescribe OxyContin for chronic non-cancer pain. By 2003, according to the Government Accountability Office ("GAO"), general practitioners represented half of all OxyContin prescribers.[78] A GAO report noted that, between 1997 and 2002, OxyContin prescriptions for non-cancer pain increased nearly ten-fold, from 670,000 to 6.2 million, versus an increase in prescriptions for treatment of cancer pain from 250,000 to 1 million; non-cancer prescriptions represented 85% of total OxyContin prescriptions. At the same time, Purdue doubled the number of its sales representatives, who received bonuses based on sales quotas and were directed to target the most prolific opioid prescribers. Total sales bonuses in 2001 were $40 million, up from $1 million in 1996. Purdue also used speakers bureaus, which put on programs at resort locations, starter coupons to attract new patients, funded new front group websites, and, even distributed plush toys and hats, which the Drug Enforcement Administration ("DEA") says had never been done before for a controlled substance. The DEA blamed Purdue's "aggressive marketing of OxyContin" for "fuel[ing] demand for the drug and exacerbat[ing] the drug's diversion.[79]

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[78] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem, supra* note 71.

[78] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem, supra* note 71.

[79] *Id.*

229. In 2001, the FDA required Purdue to narrow its approved indication to "moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time" and added new warnings relating to the drug's potential for misuse and abuse. In August of that year, the FDA wrote to Purdue to make clear that all promotional materials should prominently disclose the new label information. Yet, not 18 months later, in January 2003, in response to two ads Purdue ran in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, the FDA issued a sharply worded warning letter to Purdue:

> Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of risk. In addition, your journal advertisements fail to present in the body of the advertisements critical information regarding limitations on the indicated use of OxyContin, thereby promoting OxyContin for a much broader range of patients with pain than are appropriate for the drug. The combination in these advertisements of suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use is especially egregious and alarming in its potential impact on the public health.[80]

230. The FDA's strong language seemed to have little impact on Purdue's behavior. In 2007, Purdue entered into a $635 million settlement with the federal government to resolve civil and criminal allegations relating to its marketing of OxyContin. This was a minor cost compared to the $27 billion in sales revenue generated since the introduction of OxyContin in 1996.[81] Purdue pled guilty to a single felony count of misbranding and its chief executive officer, chief

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[80] Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Mktg., Adver., and Commc'ns , U.S. F.D.A., to Michael Friedman, Executive Vice President and C.O.O., Purdue Pharma L.P. (Jan. 17, 2003), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM168946.pdf.

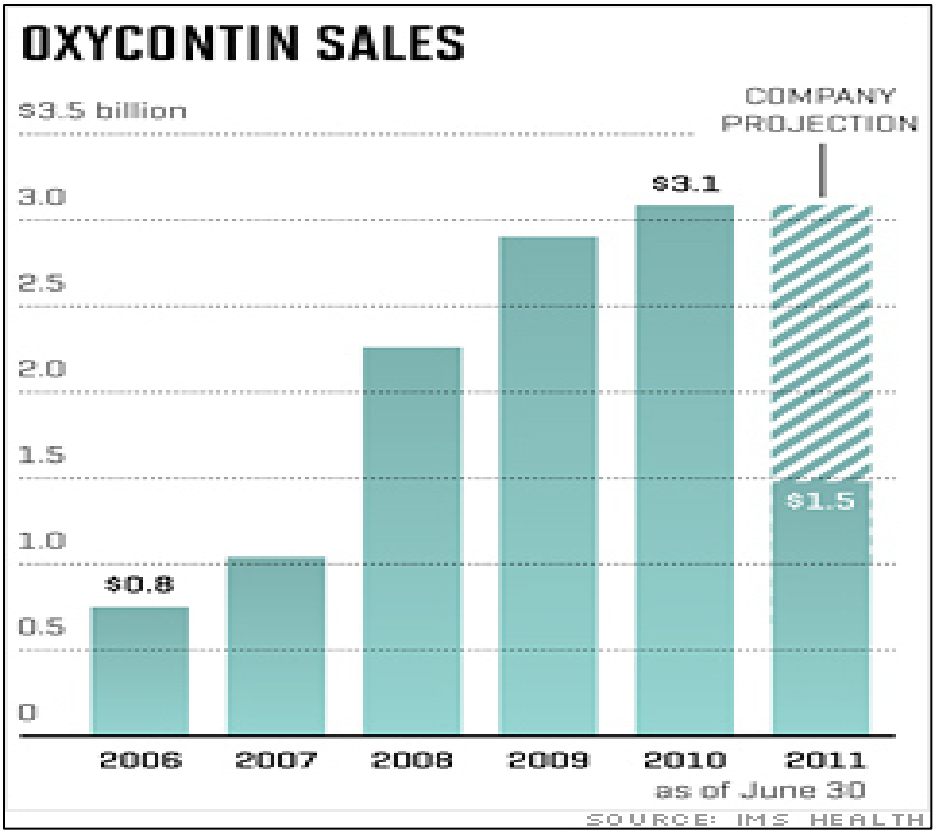
[81] Scott Glover & Lisa Girion, *OxyContin Maker Closely Guards Its List of Suspect Doctors,* Los Angeles Times (Aug. 11, 2013), articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811.

medical officer, and general counsel individually pled guilty to misdemeanor counts. Purdue admitted in its plea that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science.

231. As part of its settlement, Purdue entered into a Corporate Integrity Agreement with the United States Department of Health and Human Services-Office of Inspector General ("HHS-OIG"). Purdue agreed to refrain from deceptively marketing OxyContin, to train its employees regarding compliance with the Agreement, monitor its own compliance, and report its compliance (both independently and through an independent review organization or "IRO") to HHS-OIG.

b. Purdue continued to engage in false marketing, misrepresenting OxyContin's benefits and the risk of addiction when taken long-term for chronic non-cancer pain.

232. Despite its guilty plea, Purdue continued to deceptively market opioids. And, as a result, its sales continued to grow. OxyContin yielded $3.1 billion in revenue for Purdue in 2010, up four-fold from its 2006 sales of $800 million.



233. Purdue's direct misrepresentations, and its relationship with front groups and KOLs who advanced its deceptive marketing, are described above. Upon information and belief, Purdue deployed these doctors and front groups according to marketing strategies it developed, and also funded, directed, shaped, approved, and disseminated their misrepresentations regarding the risks, benefits, and superiority of opioids' use to treat chronic non-cancer pain.

c. Purdue was aware of, and has profited from, misuse and diversion of its opioids.

234. According to the GAO, the first public news of diversion and abuse of OxyContin became known in 2000. Among them were reports of patients arriving in emergency rooms with severe withdrawal or overdoses, hundreds of deaths, and increases in drug treatment admissions for individuals on OxyContin. Since 2000, there have been countless news reports, lawsuits, and government and other data describing the rising toll of addiction, overdose, and death from OxyContin specifically and opioids generally.

235. In 2010, Purdue reformulated OxyContin, claiming that it would reduce tampering and make it less subject to abuse. The new OxyContin cannot be reduced to a powder as easily and does not dissolve; when water is added to it, it becomes gelatinous and cannot be injected.

236. While an important step, Purdue knew that even the reformulation of OxyContin did not resolve issues of abuse and addiction. A recent article in the LOS ANGELES TIMES revealed that Purdue – since 2002 – has kept a database of 1,800 doctors suspected of inappropriately prescribing its drugs, but Purdue did not alert law enforcement or medical authorities to all but a few of these doctors.[82] This database, according to the news report, was whittled down from 3,200 doctors reported as suspicious by Purdue's sales representatives (conduct that must have been so egregious that the sales representatives forewent the chance to earn commissions on the doctors' prescriptions).

237. Purdue did not use its database of problem doctors to reduce OxyContin abuse, to rein in dangerous doctors, or to stop the potentially unlawful distribution of a controlled substance. Instead, the company presented the evidence of rogue prescribing in an effort to persuade the FDA that generic drug makers should not be allowed to copy the earlier, non-tamper resistant version of OxyContin – the same OxyContin that Purdue originally promoted as less addictive – as it is too subject to abuse.

238. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in the LOS ANGELES TIMES article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." Instead, on information and belief, Purdue continued to profit from the prescriptions of these suspicious prescribers. Psychologist, researcher, and Stanford University professor Keith Humphreys noted, "[t]hose doctors are a gold mine for

[82] Glover & Girion, *supra* note 81.

Purdue. And the whole time they're taking the money, knowing that something is wrong, and not telling anyone until it gives them a market advantage to do so. That is really disgusting."[83]

G. Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False, Unfounded and Dangerous, and Would Harm Chicago Residents.

239. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic non-cancer pain were untrue and unproven. The history of opioids, as well as research and clinical experience over the last 20 years, established that they were deeply addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to address nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

240. Moreover, Defendants intended doctors, patients, and payers to rely on their representations. Defendants closely monitored their sales and the habits of prescribing doctors, which allowed them to see sales balloon, overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CMEs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to and also watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe, patients to use, and payers to cover their opioids for chronic pain.

[83] *Id.*

H. Defendants Fraudulently Concealed their Misrepresentations

241. At all times relevant to this Complaint, Defendants took steps to avoid detection of and fraudulently conceal their deceptive marketing and conspiratorial behavior.

242. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and relied on them to vouch for the accuracy and integrity of Defendants' untrue and unsupportable statements about opioid use for chronic non-cancer pain.

243. Upon information and belief, while Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Upon information and belief, Defendants exerted their considerable influence on these promotional and "educational" materials through their funding of and relationship with KOLs and front groups, both directly and through their public relations companies.

244. Contrary to their competitive interest in promoting their own opioid products, Defendants disseminated their deceptive messages through websites that were unbranded (did not promote a specific drug) and therefore could not easily be tied to a particular drug company sponsor. Unbranded messaging created the appearance of neutrality and gave Defendants' marketing messages the appearance of unbiased medical science. [redacted] Upon information and belief, Defendants, including Purdue and Janssen, ran similar websites that masked their own direct role in developing the content.

245. Upon information and belief, Defendants also obscured their participation by extensively using the public relations companies they hired to work with front groups to produce and disseminate deceptive materials.

246. Much of Defendants' deceptive marketing occurred at medical conferences and through CMEs that were open only to registered medical professionals. Therefore, the City would have had no access to or awareness of their content.

247. Further, in addition to hiding their own role in the deceptive conduct, Defendants manipulated their promotional materials to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by the City. Only in recent months have some of the KOLs whom Defendants relied upon and promoted to spread their deceptive messages acknowledged the lack of support for their positions.

248. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their marketing strategy, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that the City now assert. The City was not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the City of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

I. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to the City of Chicago and Chicago Consumers.

249. Defendants' misrepresentations prompted doctors to prescribe, patients to take, and payers to cover opioids for the treatment of chronic non-cancer pain, believing that the benefits outweighed the risks and were better than alternative treatments. Defendants set out to overcome barriers to widespread prescribing of opioids – and succeeded – through a series of

deceptive messages designed to misrepresent the benefits, risks, and superiority of opioids over other treatments.

250. Defendants' deceptive marketing caused the use of opioids to explode. National trends—trends that also buffeted Chicago—reveal the alarming rates of opioid use. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids."[84] Indeed, "[o]pioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid."[85] A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010 even though the number of office visits in which patients complained of pain did not change; prescribing of non-opioid pain medications decreased over the same time.[86] For back pain alone – one of the most common chronic non-cancer pain conditions – the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady.[87] This increase corresponds with, and was caused by, Defendants' marketing push.

251. The sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as

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[84] Marie N. Stagnitti, *Statistical Brief #235: Trends in Outpatient Prescription Analgesics Utilization and Expenditures for the U.S. Civilian Noninstitutionalized Population, 1996 and 2006*, Agency for Healthcare Research and Quality, Fig. 6 (Feb. 2009), http://meps.ahrq.gov/mepsweb/data_files/publications/st235/stat235.pdf.

[85] Deborah Grady et al., *Opioids for Chronic Pain,* 171(16) Archives of Internal Med. 1426, 1426 (Sept. 12, 2011).

[86] Matthew Daubresse et al., *Ambulatory Diagnosis & Treatment of Nonmalignant Pain in the U.S., 2000-2010,* 51(10) Med. Care, 870-878 (Oct. 2013).

[87] John N. Mafi et al., *Worsening Trends in the Mgmt. & Treatment of Back Pain,* 173(17) Journal of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

measured by prescriptions filled and their abuse.[88] "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."[89] Opioids are involved in 40% of fatal drug overdoses – including overdoses due to illegal drugs.[90] Contrary to Defendants' misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.[91] According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for 20% of all prescription drug overdoses.[92] In 2009, there were more than twice as many deaths from prescription opioid overdoses (15,597) than from cocaine (4,350) and heroin (3,278) put together.

252. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and

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[88] Theodore J. Cicero et al., *Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States*, 16(8) Pharmacoepidemiology and Drug Safety, 827-840 (Aug. 2007).

[89] Grady, *supra* note 85, at 1426.

[90] Margaret Warner et al., *NCHS Data Brief: Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999-2006*, Centers for Disease Control & Prevention, (Sept. 2009), www.cdc.gov/nchs/data/databriefs/db22.pdf.

[91] *Results from the 2011 Nat'l Survey on Drug Use & Health: Summary of Nat'l Findings*, U.S. Dep't of Health & Human Servs. (Sept. 2012), http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.pdf.

[92] *CDC Grand Rounds: Prescription Drug Overdoses, a U.S. Epidemic*, Centers for Disease Control & Prevention (Jan. 13, 2012), www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm.

795 non-medical users.[93] Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).[94]

253. Chicago's numbers are similarly dramatic. There have been over 1,000 emergency department visits for opioid overdoses, and over 1,200 emergency department visits involving patients who were illicitly using opioids.[95] For example, estimates of visits to the emergency department in Chicago due to the misuse and abuse of prescription painkillers have been steadily increasing, with a significant increase of 65 percent between 2004 and 2011.[96]

254. By May 2014, the State of Illinois had seventy-one Certified Opioid Treatment Programs, thirty-one of which are in the City of Chicago.[97] By way of contrast, Tennessee, whose opioid epidemic is among the worst in the nation, has only twelve.[98] Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction – buprenorphine and naltrexone – were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payers at $72.5 billion.[99]

255. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new

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[93] Wilson M. Compton, *Prescription Drug Abuse: It's Not What the Doctor Ordered*, Nat'l Inst. On Drug Abuse, (May 3, 2013), www.apa.org/about/gr/science/spin/2013/05/prescription-drug-abuse.pdf.

[94] *Nat'l Estimates of Drug-Related Emergency Dep't Visits, 2004-2011,* Substance Abuse & Mental Health Servs. Admin. (2011), *http://www.samhsa.gov/data/dawn/nations/Nation_2011_NMUP.xls.*

[95] *Metro Brief Chicago*, *supra* note 6.

[96] Substance Abuse and Mental Health Services Administration, Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits. HHS Publication No. (SMA) 13-4760, DAWN Series D-39. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[97] *Opioid Treatment Program Directory,* Substance Abuse & Mental Health Servs. Admin., http://dpt2.samhsa.gov/treatment/directory.aspx

[98] *Id.*

[99] Katz, *supra* note 30.

wave of addiction, abuse, and injury. Defendants' scheme supplied both ends of the secondary market for opioids – providing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that "substantial increases in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use."[100] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.[101]

256. A significant black market in prescription opioids also has arisen, which has not only created and supplied additional addicts, but fueled other criminal activities. According to the Chicago field division of the Drug Enforcement Administration, "Street gangs, too, have become increasingly involved in prescription drug diversion."[102]

257. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals and, in 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006; nearly 80% of those who used heroin in the past year previously abused prescription opioids.[103] Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street." In the words of one federal Drug Enforcement Agency official, "Who would have ever thought in this country it would be cheaper to buy heroin than pills and obtain them more easily. That is the reality we're facing."[104]

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[100] G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) The Journal of the Am. Med. Ass'n, 1865-1866 (Nov. 14, 2012).

[101] Katz, *supra* note 30.("The most common source of abused [opioids] is, directly or indirectly, by prescription.").

[102] Thomas, *supra* note 9.

[103] NPR Staff, *With Rise of Painkiller Abuse, A Closer Look At Heroin*, NPR (Nov. 2, 2013), www.npr.org/2013/11/02/242594489/with-rise-of-painkiller-abuse-a-closer-look-at-heroin.

[104] Matt Pearce & Tina Susman, *Philip Seymour Hoffman's death calls attention to rise in heroin use*, Los Angeles Times (Feb. 3, 2014), http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204.

258. That reality holds in Chicago. Area drug treatment centers treat a significant number of patients for opioid addiction. Many of those addicted to opioids who seek treatment in Chicago treatment centers started with one prescription, liked how opioids made them feel, and stayed on them. Eventually, they became addicted, often after just a few months on opioids. Those who seek treatment often do so after a precipitating life event—either losing a job or being confronted by family—or after turning to criminal activity such as prostitution and theft to sustain their addiction. If their fates are consistent with patterns nationally some of them will overdose – some fatally, some not. Others will die prematurely from related causes – falls, traffic accidents, or assaults or from premature heart or neurological disease that hastens their death by 10 or 20 years. Those who do not relapse face a lifetime of treatment, including prolonged counseling or reliance on maintenance drugs such as methadone or buprenorphine.

259. The overprescribing of opioids for chronic non-cancer pain has given young children access to opioids, nearly all of which were prescribed for adults in their household. One study documented over 9,000 children nationally exposed to prescription opioids, with a median age of two years old. The number of exposures in young children was correlated to the number of prescriptions in the area.[105]

260. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS") also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born. They cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit

[105] . J. Elise Bailey et al., *The under recognized toll of prescription opioid abuse on young children*, 53(4) Annals of Emergency Med., 419-424 (Apr. 2009).

disorder, lack of impulse control, and a higher risk of future addiction.[106] When untreated, NAS can be life-threatening.[107] In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.[108] According to data from Tennessee, which has most closely studied the issue, 52% of mothers of NAS newborns used only drugs prescribed to them; another 20% used a mix of their own prescriptions and illicitly obtained drugs.[109]

J. Defendants' Fraudulent and Deceptive Marketing of Opioids Caused False Claims for Payment to Be Submitted to the City

261. The City provides comprehensive health care protection, including prescription drug benefits, to its employees and retirees. These benefits are provided under various health plans that the City self-insures, including a preferred provider organization ("PPO"), a health maintenance organization ("HMO"), and a plan that covers retirees who are not yet on Medicare and provides supplemental coverage to those retirees who are on Medicare. The prescription drug plan under the PPO is self-insured: the costs of prescription drugs are passed on directly to the City, which reimburses the plans for any prescription costs the plans incur. Throughout the relevant time period for this action, the PPO's prescription drug costs have been passed on directly to, and paid by, the City.

262. The HMO's prescription drug coverage has been self-insured at various times throughout the relevant time period. Before July 2006, the City paid the premiums for the HMO plans, which in turn covered the cost of prescription drugs. Between July 2006 and December 2009, the City paid the premiums for the HMO plan to Unicare, which in turn covered the cost of

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[106] *Transcript of Impact of Approved Drug Labeling – Part 15 Hearing* at 116-121, F.D.A. (Feb. 7, 2013), www.fda.gov/downloads/Drugs/NewsEvents/UCM342700.pdf.

[107] *See* Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation & Research, to Petitioner, Nat'l Advocates for Pregnant Women (Apr. 16, 2014).

[108] Stephen W. Patrick et al., *Neonatal Abstinence Syndrome & Associated Health Care Expenditures*, 307(18) Journal of the Am. Med. Ass'n 1934, 1937 (May 9, 2012).

[109] Jonel Aleccia, *'Just flooding us': Tenn. spike in drug-dependent newborns is warning to nation*, NBC News (Oct. 11, 2013), *http://www.nbcnews.com/health/kids-health/just-flooding-us-tenn-spike-drug-dependent-newborns-warning-nation-f8C11375654.*

prescription drugs, but during that same time period, the City also had an HMO with Blue Cross/Blue Shield, which passed the costs of prescriptions drugs directly on to the City. From January 2010 to December 2011, both HMO plans were operated by Blue Cross/Blue Shield and the costs of prescriptions drugs were paid directly by the City. From January 2012 to December 2013, two HMO plans were merged into one HMO plan and the City paid premiums to the HMO plan, which in turn covered the cost of prescription drugs. Since January 1, 2014, the City's prescription drug coverage under the HMO is once again self-insured and has been directly paying the costs of prescription drugs under the HMOs.

263. The City's self-insured health plans only cover the cost of prescription drugs that are "Medically Necessary" and dispensed for a FDA-approved purpose. Prescription drugs that are not "Medically Necessary" or that are dispensed for a non-FDA-approved purpose are expressly excluded from coverage under the City's plans. Under the plans, a "Medically Necessary" prescription is that which is "customary for the treatment or diagnosis of an Illness or Injury, and is consistent with generally accepted medical standards."

264. Defendants specifically targeted doctors with their fraudulent marketing efforts in an effort to persuade doctors that opioids have real benefits and minimal risks and are superior to alternate treatments. Doctors relied in good faith on Defendants' false representations to prescribe opioids for chronic non-cancer pain, and Defendants reaped the benefits of increased opioid sales and profits.

265. In Chicago, Defendants' fraudulent marketing prompted doctors to prescribe opioids for chronic non-cancer pain to patients covered by the City's health plans. Doctors were and are bound by the provider agreements that entitle them to participate in the City's health plans. These agreements permit doctors to charge only for services that are "medically necessary," which requires that treatments be "in accordance with generally accepted standards of medical practice," and "clinically appropriate . . . and considered effective for the patient's illness, injury or disease." Generally accepted standards of medical practice is defined in the agreement as standards "based on credible scientific evidence."

266. Doctors submit claims directly to the City's health plan for the costs associated with prescribing opioids, including office visits and toxicology screens for patients prescribed opioids. In addition, prescriptions for opioids for patients covered by the City's self-insured health plans are filled by pharmacies, which submit claims for reimbursement to the City's health plan. In prescribing and filling prescriptions for chronic opioid therapy, doctors and pharmacists expressly and impliedly certify the prescriptions as "Medically Necessary," and—at least with respect to the self-insured plans (the PPO, and the various self-insured HMOs)—the health plans authorize payment from City funds.

267. But as the scientific evidence makes clear, opioid treatments for chronic non-cancer pain are not "Medically Necessary" as the City health plans define that term: Opioid treatment for chronic non-cancer pain is not a customary treatment, not consistent with generally accepted medical standards, not effective, and not based on credible scientific evidence.

268. Defendants' fraudulent marketing scheme also caused the City to pay for opioids for non-FDA approved purposes. Cephalon's Fentora, for example, was specifically marketed for non-FDA approved uses. Physicians, in turn, wrote prescriptions for Fentora for non-FDA approved uses, causing the self-insured health plans to authorize and the City to pay for those prescriptions. A review of City records reveals that opioids were prescribed for other non-FDA approved uses, including depression.

269. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by the deceptive marketing of Defendants, as laid out above; Defendants' ability to seed—through fraud—medical practice that supported the use of opioids for chronic non-cancer pain should not entitle them to profit from that fraud.

270. Defendants' fraudulent marketing scheme also caused the City to pay for opioid treatments that were worthless. Not only did chronic opioid therapy often provide no benefit in treating chronic long term pain or improving patients' function, it often worsened the pain and subjected patients to significant risks and adverse effects.

271. Since 2007, the City has paid—just in the PPO plan alone—nearly 400,000 claims submitted to it for the payment of opioid prescription fills with a total cost to the City of nearly $9,500,000. As a 2008 presentation to the FDA by the Group Health Research Institute made clear, 87% of all opioids dispensed were to chronic pain patients using opioids long-term, whereas only 13% were for acute or cancer pain patients.[110] Based on this, and upon information and belief, approximately 87% of the opioid fills that the City has paid for have been for non-"Medically Necessary" and/or non-FDA approved uses.

272. Although Defendants' collective promotion led to the total City spend on opioids, the City has spent substantial sums on each Defendant's opioids. Just from the PPO and just since 2007, the City has paid 7,949 claims, totaling $2,548,497.99 for Purdue opioids; 172,438 claims, totaling $1,553,867.3 for Actavis opioids; 2,559 claims, totaling $701,971.35 for Endo opioids; 1,564 claims, totaling $272,440.90 for Janssen opioids; and 105 claims, totaling $139,640.65 for Cephalon opioids. These figures do not reflect the cost to the City of other opioid prescriptions caused by Defendants' marketing or other costs laid out in Section I, below.

K. Defendants' Fraudulent and Deceptive Marketing of Opioids Has Caused the City to Incur Related Costs

273. In addition to paying for the costs of filling opioid prescriptions pursuant to its employee and retiree health plans, the City has suffered significant additional damages as a result of the Defendants' deceptive promotion. The City and its health plans have paid costs that include, but are not limited to, the costs immediately associated with prescribing opioids, such as doctors' visits and toxicology screens to monitor patients' drug-taking, as well as other costs imposed by long-term opioid use, abuse, and addiction, such as hospitalizations for opioid overdoses, drug treatment for individuals addicted to opioids, intensive care for infants born addicted to opioids, and more. In addition, Defendants have imposed upon the City costs beyond

[110] *See* Von Korff, *supra* note 5.

its health plans, providing emergency services, funding addiction treatment, and paying other costs imposed by the epidemic of opioid use and abuse in the City.

VI. COUNT ONE

CONSUMER FRAUD

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 2-25-090 AGAINST ALL DEFENDANTS

274. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

275. The Chicago Municipal Code § 2-25-090 makes it unlawful for a business to "engage in any act of consumer fraud, unfair method of competition, or deceptive practice while conducting any trade or business in the city," including "any conduct constituting an unlawful practice under the Illinois Consumer Fraud and Deceptive Business Practices Act." The Illinois Consumer Fraud and Deceptive Business Practices Act, 735 ILCS 505/2, makes unlawful, among other things, "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' . . ."

276. Defendants have engaged in unlawful, deceptive, and unfair business practices in violation of the Municipal Code as set forth above.

277. Defendants' practices as described in the Complaint are deceptive business practices that violate Chicago Municipal Code § 2-25-090 because the practices were and are intended to deceive consumers and occurred and continue to occur in the course of conduct involving trade and commerce in the City.

278. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 2-25-090 by making and disseminating untrue, false, and misleading statements to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic non-cancer pain.

279. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 2-25-090 by making statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic non-cancer pain.

280. Defendant Purdue made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;
- Posting on the internet misleading statements and pamphlets concerning the risk of addiction and the misleading concept of pseudoaddiction;
- Distributing brochures to doctors that included misleading statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributed and assisted in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Endorsing and assisting in the distribution of CME programs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the dissemination of scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and
- Exclusively disseminating misleading statements in education materials to Chicago hospital doctors and staff while purportedly educating them on new pain standards created by JCAHO.

281. Defendant Endo made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, controlling, endorsing and sponsoring patient education materials and programs that contained misleading statements;
- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the ability of opioids to improve function long-term, and the efficacy of opioids long-term, in the treatment of chronic non-cancer pain;
- Facilitating the posting on the internet of misleading statements and pamphlets concerning the risk of addiction, the misleading concept of pseudoaddiction and misleading claims that long-term treatment of opioids improves function;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations – including over $10 million to the organization responsible for many of the most egregious misrepresentations – that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting the in the dissemination of literature written by pro-opioid KOLs that contained false, misleading and untrue statement concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the dissemination of scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life; and
- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain.

282. Defendant Janssen made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, controlling, endorsing and sponsoring patient education materials and programs that contained misleading statements concerning the risk of addiction;
- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the efficacy of opioids long-term in the treatment of chronic non-cancer pain;

- Facilitating the posting of misleading statements and pamphlets, concerning the risk of addiction, the misleading concept of pseudoaddiction and misleading claims that long-term treatment of opioids improves function;

- Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain in the elderly;

- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeted the elderly in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain in the elderly; and

- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain.

283. Defendant Cephalon made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, endorsing and sponsoring patient education materials that contained misleading statements;

- Endorsing, directly distributing and assisting in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CME programs containing untrue, false and misleading statements concerning the use of opioids approved only for cancer pain to treat chronic non-cancer pain, and which did not concern cancer pain;

- Assisting in the dissemination of scientific studies that misleadingly concluded Cephalon's opioids (approved only for cancer pain) are safe and effective for the long-term treatment of chronic non-cancer pain; and

- Targeting its marketing to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists and workers' compensation programs serving chronic pain patients.

284. Defendant Actavis made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;

- Instructing its sales force to make false, misleading and untrue statements to doctors concerning the ability of opioids to improve function long-term, in the treatment of chronic, non-cancer pain.

- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the risk of addiction in the long-term treatment of chronic, non-cancer pain.

- Providing significant financial support to pro-opioid key opinion leader who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain.

285. Defendants knew at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and therefore likely to deceive the public. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks of opioids.

286. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids untrue, false, and misleading. In omitting and concealing these material facts, Defendants intended to cause Chicago consumers and payers of opioid prescriptions to rely on those omissions and concealments.

287. All of this conduct, separately and collectively, was intended to deceive Chicago consumers who used or paid for opioids for chronic non-cancer pain, Chicago physicians who prescribed opioids for chronic non-cancer pain, and Chicago payers, including the City, who purchased, or covered the purchase of, opioids for chronic non-cancer pain.

288. Defendants' practices as described in the Complaint are also unfair practices that violated Chicago Municipal Code § 2-25-090 because the practices offend public policy; are immoral, unethical, oppressive, or unscrupulous; or caused substantial injury to consumers.

289. Defendants' practices in deceptively exaggerating the benefits and minimizing the risks of these addictive drugs offend deep-seated public policies aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs, and preventing addiction and the sale and use of illegal drugs, among others, as described above. Defendants have sacrificed their duties to their customers and to public health in favor of blockbuster profits. They have caused and continue to cause grievous harm to consumers. The staggering rates of opioid use, abuse, and addiction resulting from Defendants' marketing efforts have caused substantial injury, including, but not limited to:

a. Upwards of 30% of all adults have used opioids, with the vast majority of the use stemming from prescribing for chronic non-cancer pain conditions. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
b. Children, too, have been harmed by opioids. They have been exposed to medications prescribed to family members or others, resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among Chicago teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and potentially lasting developmental impacts.
c. Chicagoans who have never taken opioids also have also been injured. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
d. More broadly, opioid use and misuse have driven Chicagoans' health care costs higher.

e. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

f. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process.

g. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids have increased the demands on emergency services and law enforcement in the City.

h. All of this has caused substantial injuries to consumers – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes.

290. Defendants' practices have also violated Chicago Municipal Code § 2-25-090 because the practices violate the Illinois Consumer Fraud and Deceptive Business Practices Act, which is incorporated into the Chicago Municipal Code § 2-25-090 by reference. The Illinois Consumer Fraud and Deceptive Business Practices Act makes unlawful, among other things, "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' . . ." 735 ILCS § 505/2.

291. Defendants' employed several practices proscribed by the Uniform Deceptive Trade Practices Act:

292. By, among other things, using front groups, KOLs, and others to peddle their misrepresentations, by influencing the creation of misleadingly pro-opioid treatment guidelines and CMEs, and by distorting the scientific evidence for opioid use for chronic non-cancer pain, Defendants made it appear that opioids had sponsorship and qualities that opioids do not have. In so doing, Defendants:

- "cause[d] likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services." 735 ILCS § 510/2(a)(2).

- "cause[d] likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another." 735 ILCS § 510/2(a)(3).
- "represent[ed] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have." 735 ILCS § 510/2(a)(5).

293. By, among other things, deceptively characterizing the risks of NSAIDs in order to promote opioids, Defendants "disparage[d] the goods, services, or business of another by false or misleading representation of fact." 735 ILCS § 510/2(a)(8).

294. Altogether, Defendants "engage[d] in any other conduct which similarly creates a likelihood of confusion or misunderstanding." 735 ILCS § 510/2(a)(12).

295. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and/or other benefits, which they would not have received if they had not engaged in the violations of Chicago Municipal Code § 2-25-090 as described in this Complaint.

296. By reason of the Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count One of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 2-25-090; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' consumer fraud, unfair competition, and deceptive practices; (d) compelling Defendants to pay civil penalties up to $10,000 per violation pursuant to § 2-25-0909(f) for each day the violations occurred; (e) compelling Defendants to disgorge their ill-gotten profits; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

VII. COUNT TWO

MISREPRESENTATIONS IN CONNECTION WITH SALE OR ADVERTISEMENT OF MERCHANDISE

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 4-276-470 AGAINST ALL DEFENDANTS

297. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

298. Section 4–276–470(1) of the Chicago Municipal Code states:

> It shall be unlawful for any person to act, use or employ any deception, fraud, false pretense, false promise or misrepresentation, or to conceal, suppress or omit any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale * * * or advertisement of any merchandise.

299. Defendants' practices as described in the Complaint violated Chicago Municipal Code § 4-276-470(1) because the practices were intended to deceive doctors, consumers, and other health care payers and occurred in connection with sale or advertisement of any merchandise.

300. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 4-276-470(1) by making and disseminating deceptions and misrepresentations to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic non-cancer pain.

301. Defendants knew at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and failed to disclose material risks and were therefore likely to deceive doctors, consumers, and other health care payers. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks of opioids.

302. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids untrue, false, and misleading. In

omitting and concealing these material facts, Defendants intended to cause Chicago doctors, consumers, and other payers of opioid prescriptions to rely on those omissions and concealments.

303. All of this conduct, separately and collectively, was intended to deceive Chicago consumers who used or paid for opioids for chronic non-cancer pain, Chicago physicians who prescribed opioids for chronic non-cancer pain, and other payers, including the City, who purchased, or covered the purchase of, opioids for chronic non-cancer pain.

304. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of Chicago Municipal Code § 4-276-470(1) as described in this Complaint.

305. By reason of the Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Two of the Complaint; Chicago Municipal Code(b) compelling Defendants to pay civil penalties up to $2000 per violation pursuant to § 4-276-480 for each day the violations occurred; and (c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

VIII. COUNT THREE

FALSE STATEMENTS TO THE CITY

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-21-010, *ET SEQ.* AGAINST ALL DEFENDANTS

306. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

307. Section 1-21-010(a) of the Chicago Municipal Code provides, in pertinent part:

> Any person who knowingly makes a false statement of material fact to the city in violation of any statute, ordinance or regulation, or who knowingly makes a false statement of material fact to the city in connection with any application, report,

> affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit, is liable to the city for a civil penalty of not less than $500.00 and not more than $1,000.00, plus up to three times the amount of damages which the city sustains because of the person's violation of this section. A person who violates this section shall also be liable for the city's litigation and collection costs and attorney's fees. The penalties imposed by this section shall be in addition to any other penalty provided for in the municipal code.

308. Section 1-21-010(d) of the Chicago Municipal Code provides, in pertinent part, that:

> For the purposes of Chapter 1-21 of this Code, a person knowingly makes a false statement of material fact when that person (i) makes a statement of material fact with actual knowledge that the statement was false, or (ii) makes a statement of material fact with knowledge of facts or information that would cause a reasonable person to be aware that the statement was false when it was made, or (iii) signs, certifies, attests, submits or otherwise provides assurances, or causes any other person to sign, certify, attest, submit or otherwise provide assurances, that a statement of material fact is true or accurate in deliberate ignorance or reckless disregard of the truth or falsity of the statement. For purposes of this section, a person who fails to make a reasonable investigation to determine the accuracy, truthfulness or completeness of any material fact acts in deliberate ignorance or reckless disregard of the truth or falsity of the material fact.

309. Subsection 1-21-020 of the Chicago Municipal Code provides, in pertinent part, that:

> Any person who aids, abets, incites, compels or coerces the doing of any act prohibited by this chapter shall be liable to the city for the same penalties for the violation.

310. Defendants have incited or caused others to submit false statements of material fact to the City. Through their scheme to illegally and deceptively promote opioids in an effort to further opioids sales, Defendants aided, abetted, incited, or caused doctors, pharmacists, and/or agents of the health plans to sign, certify, attest, submit or otherwise provide assurances, expressly or impliedly, that opioids to treat chronic non-cancer pain were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain.

311. If the City had known of the false statements disseminated by Defendants in support of opioids and that doctors, pharmacists, and/or agents of the health plan were certifying and/or determining that opioids were "medically necessary" based on those false statements, the City would have refused to authorize payment for opioid prescriptions.

312. By virtue of the above-described acts, Defendants aided, abetted, incited, and caused others to make false statements of material fact to the City in connection with claims to pay for opioids to treat chronic pain, within the meaning of Chicago Municipal Code § 1-21-010 and 1-21-020.

313. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Three of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-010 and/or 1-21-020; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' false statements; (d) compelling Defendants to pay civil penalties up to $1,000 for each false statement made to the City that the Defendants aided, abetted, incited, or caused; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

IX. COUNT FOUR

FALSE CLAIMS

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-22-020 AGAINST ALL DEFENDANTS

314. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

315. Section 1-22-020 of the Chicago Municipal Code is violated when any person "(1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the city; [or] (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid."

316. Section 1-22-010 of the Chicago Municipal Code defines a claim as "any request or demand, whether under a contract or otherwise, for money or property which is made by a city contractor, grantee, or other recipient if the city is the source of any portion of the money or property which is requested or demanded, or if the city will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded."

317. Defendants, through their deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used a false statement to get a false or fraudulent claim for payment or approval by the City.

318. Defendants knew, or by the exercise of reasonable care should have known, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting the City's health plans and other insurers to reimburse or pay for opioids. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic non-cancer pain.

319. The Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic non-cancer pain that were presented to the City's health plans for payment. The City

only covers the cost of prescription drugs that are "medically necessary." Opioids, however, are not "medically necessary" to treat chronic non-cancer pain. Yet doctors, pharmacists, and/or other agents of the health plans, expressly or impliedly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the City were for uses that were not approved by the FDA and therefore, were not medically necessary.

320. Defendants knew or should have known that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic non-cancer pain, which were dispensed as a consequence of Defendants' fraud.

321. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants and that doctors, pharmacies, and/or the health plans were certifying and/or determining that opioids were medically necessary, the City would have refused to authorize payment for opioid prescriptions.

322. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic non-cancer pain were paid by the City.

323. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City to approve and pay such false and fraudulent claims.

324. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

325. Defendants' fraudulent marketing scheme also caused the City to pay false claims in that the scheme also caused the City to pay for opioids that were worthless. As described

above, opioids provide no benefit to many patients treated with them long-term for chronic pain; in many cases, it worsened the pain and subjected patients to significant risks and adverse effects.

326. The City, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

327. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

328. Each Defendant is responsible for the claims submitted and the amount the City spent on each Defendant's opioids.

329. Because Defendants acted concurrently and/or collaboratively in carrying out a common fraudulent scheme—causing others to submit false claims for opioids which were paid by the City—Defendants are jointly and severally liable for the City's total spend on non-medically necessary opioids to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Four of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-020; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' false statements; (d) compelling Defendants to pay civil penalties up to $10,000 for each false or fraudulent claim the Defendants caused to be presented to an official or employee of the City for payment or approval; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including

attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

X. COUNT FIVE

CONSPIRACY TO DEFRAUD BY GETTING FALSE OR FRAUDULENT CLAIMS PAID OR APPROVED BY THE CITY

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-22-020 AGAINST ALL DEFENDANTS

330. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

331. Section 1-22-020 of the Chicago Municipal Code is violated when any person "(1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the city; [or] (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid."

332. Defendants conspired to defraud the City by getting a false or fraudulent claims allowed or paid, by acting in concert in a comprehensive scheme to defraud the City while illegally and deceptively promoting opioids in an effort to further opioids sales.

333. Defendants knowingly and voluntarily engaged in a concerted scheme to promote the widespread use of opioids for the treatment of chronic non-cancer pain directly through their own publications and employees, and indirectly, through seemingly independent thought-leaders, advocacy groups, and professional societies, by making, funding, suggesting, editing, approving, and distributing untrue, false, and misleading statements and representations to doctors and patients. The concerted scheme was entered into for the purpose of getting insurers, including the City's health plans, to reimburse or pay for opioids.

334. Defendants' common scheme was carried out through their common funding of the same front groups, CMEs and KOLs, their common advocacy through and participation in the Pain Care Forum, their coordinated marketing messages, and other steps.

335. Because of the Defendants' scheme, doctors wrote prescriptions for opioids to treat chronic non-cancer pain that were submitted to the City's health plans for payment, which only covers the cost of "medically necessary" prescriptions and those that are prescribed for FDA-approved uses. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain. Yet doctors, pharmacists, and/or other agents of the health plans explicitly or implicitly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the City were for uses that were not approved by the FDA and therefore were not medically necessary.

336. Defendants knew or should have known that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic non-cancer pain, which were dispensed as a consequence of Defendants' fraud.

337. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants in support of opioids and that doctors, pharmacies, and/or the health plans were certifying and/or determining that opioids were medically necessary based on those false statements, the City would have refused to authorize payment for opioid prescriptions.

338. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic non-cancer pain were paid by the City.

339. By virtue of the above-described acts, Defendants conspired to defraud the City by getting a false or fraudulent claim allowed or paid.

340. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

341. Defendants' fraudulent marketing scheme also caused the City to pay false claims in that the scheme also caused the City to pay for opioids that were worthless. As described above, opioids provide no benefit to many patients treated with them long-term for chronic pain; in many cases, it worsened the pain and subjected patients to significant risks and adverse effects.

342. The City, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

343. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

344. Each Defendant is responsible for the claims submitted and the amount the City spent on each Defendant's opioids.

345. Because Defendants acted concurrently and/or collaboratively in carrying out a common fraudulent scheme—causing others to submit false claims for opioids which were paid by the City—Defendants are jointly and severally liable for the City's total spend on non-medically necessary opioids to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Five of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-020; (c) compelling Defendants to pay restitution of any money acquired by Defendants' false statements; (d) compelling Defendants to

pay civil penalties up to $10,000 for each instance Defendants made or used false records and statements and caused false statements and records to be used to get a false or fraudulent claim paid or approved by the City; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (f) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XI. COUNT SIX

RECOVERY OF CITY COSTS OF PROVIDING SERVICES VIOLATIONS OF THE CHICAGO MUNICIPAL CODE § 1-20-020 AGAINST ALL DEFENDANTS

346. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

347. Section 1-20-020 of the Chicago Municipal Code provides, in pertinent part:

> Any person who causes the city or its agents to incur costs in order to provide services reasonably related to such person's violation of any federal, state or local law, or such person's failure to correct conditions which violate any federal, state or local law when such person was under a legal duty to do so, shall be liable to the city for those costs. This liability shall be collectible in the same manner as any other personal liability.

348. The defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

(1) violating Chicago Municipal Code § 2-25-090;

(2) violating Chicago Municipal Code § 4-276-470;

(3) violating Chicago Municipal Code § 1-21-010;

(4) violating Chicago Municipal Code § 1-22-020;

(5) violating Chicago Municipal Code § 1-20-020;

(6) violating 720 ILCS § 5/17-10.5;

(7) committing common law fraud; and

(8) committing common law unjust enrichment.

349. The City has incurred costs reasonably related to Defendants' violations of federal, state, or local laws.

350. The City has incurred the costs of paying for opioids prescribed for chronic non-cancer pain and related costs through its health plans, and these costs are reasonably related to Defendants' unlawful scheme.

351. The City's health plans have paid costs that include, but are not limited to, the costs immediately associated with prescribing opioids, such as doctors' visits and toxicology screens to monitor patients' drug-taking, as well as other costs imposed by long-term opioid use, abuse, and addiction, such as hospitalizations for opioid overdoses, drug treatment for individuals addicted to opioids, intensive care for infants born addicted to opioids, and more. In addition, Defendants have imposed upon the City costs beyond its health plans, such as providing emergency services, funding addiction treatment, and paying other costs imposed by the epidemic of opioid use and abuse in the City.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Six of the Complaint; (b) compelling Defendants to pay the costs the City incurred that were reasonably related to the Defendants' violations of federal, state, or local law; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XII. COUNT SEVEN

INSURANCE FRAUD VIOLATIONS OF 720 ILCS 5/17-10.5 AGAINST ALL DEFENDANTS

352. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

353. 720 ILCS § 5/17-10.5(a)(1) provides in pertinent part:

> (1) A person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false

> claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.

354. 720 ILCS § 5/17-10.5(e)(1) provides in pertinent part:

> Civil damages for insurance fraud. A person who knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of any insurance company by the making of a false claim or by causing a false claim to be made on a policy of insurance issued by an insurance company, or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property, shall be civilly liable to the insurance company or self-insured entity that paid the claim or against whom the claim was made or to the subrogee of that insurance company or self- insured entity in an amount equal to either 3 times the value of the property wrongfully obtained or, if no property was wrongfully obtained, twice the value of the property attempted to be obtained, whichever amount is greater, plus reasonable attorney's fees.

355. Through their illegal and deceptive promotion of opioids, Defendants knowingly caused false claims to be made to the City's health plans, which are self-insured, and knowingly obtained or caused to be obtained through deception the property of the City in payments for those false claims.

356. The Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic non-cancer pain that were presented to the City's health plans, which cover City employees and retirees, for payment.

357. Further, the City only covers the cost of services, tests, and prescription drugs that are "medically necessary" and prescribed for an FDA-approved use. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain.

358. Doctors, pharmacists, or other agents of the health plans, explicitly or implicitly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the

City were for uses that were not approved by the FDA and therefore, were not medically necessary.

359. The misrepresentations were material because if the City had known of the false statements disseminated by Defendants and that doctors, pharmacies, and/or the health plans certified and/or determined that opioids were medically necessary based on those false statements, the City would have refused to authorize payment for opioid prescriptions. The City is a self-insured entity and directly covers the cost of prescription drugs for City employees and retirees.

360. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made false claims with the intent to induce the City to approve and pay such false and fraudulent claims.

361. By reason of Defendants' insurance fraud, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription to be filled, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Seven of the Complaint; (b) compelling Defendants to pay three times any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XIII. COUNT EIGHT

CIVIL CONSPIRACY
VIOLATIONS OF THE COMMON LAW PROHIBITION AGAINST CIVIL CONSPIRACY
AGAINST ALL DEFENDANTS

362. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

363. Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

364. Defendants' common scheme was carried out through their common funding of the same front groups, CMEs and KOLs, their common advocacy through and participation in the Pain Care Forum, their coordinated marketing messages, and other steps.

365. The defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

(1) violating Chicago Municipal Code § 2-25-090;

(2) violating Chicago Municipal Code § 4-276-470;

(3) violating Chicago Municipal Code § 1-21-010;

(4) violating Chicago Municipal Code § 1-22-020;

(5) violating Chicago Municipal Code § 1-20-020;

(6) violating 720 ILCS § 5/17-10.5;

(7) committing common law fraud; and

(8) committing common law unjust enrichment.

366. By reason of the Defendants' unlawful acts, the City has been damaged and continues to be damaged by paying for the costs of opioid prescriptions for chronic non-cancer pain and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Eight of the Complaint; (b) compelling Defendants to pay the City's direct and consequential damages; and

(c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XIV. COUNT NINE

COMMON LAW FRAUD AGAINST ALL DEFENDANTS

367. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

368. Defendants made false statements of material fact that they knew were false to induce the City to act; the City relied on Defendants' false statements, relied on others who relied on Defendants' false statements, or both; and was damaged as a result.

369. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' and seemingly truthful statements about opioids untrue, false, and misleading. In omitting and concealing these material facts, Defendants intended to cause Chicago consumers and payers of opioid prescriptions to rely on those omissions and concealments.

370. Defendants engaged in this scheme because they intended prescription drug payers, including the City, to rely on its statements about the safety and efficacy of opioids and rely on its omissions about the risks of opioids.

371. The City relied on Defendants' statements or relied on others who relied on Defendants' statements about the risks, benefits, and superiority of opioids for the treatment of chronic non-cancer pain when it paid for prescriptions for opioids to treat chronic non-cancer pain. Had the City known about the false statements disseminated by Defendants in support of opioids for chronic non-cancer pain, the City would have refused to authorize payment for such opioid prescriptions.

372. By reason of the Defendants' fraud, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000, and suffered

additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Nine of the Complaint; (b) compelling Defendants to pay restitution of any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; (d) compelling Defendants to pay punitive damages because their false representations were wantonly and designedly made; and (e) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XV. COUNT TEN

UNJUST ENRICHMENT

VIOLATIONS OF THE COMMON LAW PROHIBITION ON UNJUST ENRICHMENT AGAINST ALL DEFENDANTS

373. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

374. Defendants have unjustly retained a benefit to the City's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

375. By illegally and deceptively promoting opioids, Defendants have unjustly enriched themselves at the City's expense. The City has made payments for opioid prescriptions and treatments, and Defendants benefited from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the City lacks a remedy provided by law.

376. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Ten of the

Complaint; (b) compelling Defendants to disgorge all unjust enrichment to the City; and (c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

DATED: June 2nd, 2014.

Respectfully submitted,

STEPHEN R. PATTON
Corporation Counsel, City of Chicago

BY: Stephen R. Patton

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IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CITY OF CHICAGO,
a municipal corporation,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; and ACTAVIS PLC,

Case No. 2014 L 005854

Defendants.

To: ***See attached certificate of service***

AMENDED NOTICE OF MOTION

On **June 12, 2014** at **9:00 a.m.**, or as soon thereafter as counsel may be heard, Petitioner, City of Chicago, by its attorney, Corporation Counsel Stephen R. Patton, shall appear before the Honorable Judge Sanjay Tailor, or any Judge sitting in his stead, in the courtroom usually occupied by him in Room 2407, Daley Center, Chicago, IL, and then and there present the attached **Plaintiff City of Chicago's (1) Ex Parte Motion for Leave to File its First Amended Complaint, and (2) Motion For Leave To Initially File An Unredacted Complaint Under Seal With A Request That The Court, After Due Review, Enter An Order Unsealing The Unredacted Complaint**.

Dated: June 9, 2014

Respectfully submitted,

STEPHEN R. PATTON
Corporation Counsel for the City of Chicago

By: Fiona A. Burke

Michael J. Dolesh
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CERTIFICATE OF SERVICE

The undersigned, an attorney, hereby certify that I caused a copy of this **Notice of Motion** and **Plaintiff City of Chicago's (1) Ex Parte Motion for Leave to File its First Amended Complaint, and (2) Motion For Leave To Initially File An Unredacted Complaint Under Seal With A Request That The Court, After Due Review, Enter An Order Unsealing The Unredacted Complaint** to be served by hand delivery by 4 p.m. on this the 9th day of June, 2014, to the following:

Janssen Pharmaceuticals, Inc.
The CT Corporation System
208 S. LaSalle Street
Suite 814
Chicago, IL 60604

Scott D. Stein
Michael Doss
Sidley Austin LLP
One South Dearborn
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By: Fiona A. Burke

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IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CITY OF CHICAGO,

a municipal corporation,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; and ACTAVIS PLC,

Case No.: 2014L005854

Defendants.

PLAINTIFF CITY OF CHICAGO'S EX PARTE MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT

Plaintiff, the City of Chicago ("City"), by its Corporation Counsel Stephen R. Patton, moves this Honorable Court for the entry of an order granting it leave to file its First Amended Complaint *instanter*, pursuant to 735 ILCS 5/2-616. In support thereof, the City states as follows:

1. The City filed its original complaint in this matter on June 2, 2014.

2. The City now seeks to amend the Complaint in order to add additional defendants that are subsidiary companies or predecessor companies of the already-named Defendants.

3. 735 ILCS 5/2-616 provides that "[a]t any time before final judgment amendments may be allowed on just and reasonable terms, introducing any party who ought to have been joined as . . . defendant." Allowing the City to amend its complaint now will enable it to join additional

Defendants who ought to be joined in the mater.

4. In the course of attempting service, the City has discovered additional subsidiaries and predecessor companies to the already-named Defendants that should be named in the Complaint. Specifically, the City seeks to add Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc., which are predecessor companies of already-named Defendant, Janssen Pharmaceuticals, Inc. The City also seeks to add Endo Health Pharmaceuticals, Inc., a wholly-owned subsidiary of already-named Defendant Endo Health Solutions, Inc. The City also seeks to add Actavis, Inc.; Watson Pharmaceuticals, Inc. now known as Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; and Actavis Pharma, Inc. formerly known as Watson Pharma, Inc. All of these entities are either direct or indirect subsidiaries of already-named Defendant Actavis plc.

5. Allowing the City to amend will allow the City to sustain its suit against all proper Defendants and will not prejudice Defendants in any way. Only Janssen Pharmaceuticals, Inc. has been officially served with the Complaint. Amendment is necessary to capture the relevant Defendants in part because of the complex structures the Defendants use to operate. During the relevant time period, upon information and belief, the Janssen, Endo, and Actaivs entities have undergone several reorganizations and name changes. By way of illustration, upon information and belief, Defendant Actavis plc has changed its name three times in the past calendar year and operates through over 270 subsidiaries, 77 of which are in the United States alone.

6. The proposed amendment does not include any substantive changes to the allegations of the Complaint.

WHEREFORE, the City prays this Honorable Court for the entry of an order granting it leave to file its First Amended Complaint, a copy of which is attached hereto as **Exhibit A**, *instanter*, or for such other relief as this Court deems just and appropriate.

June 9, 2014

Respectfully submitted,

STEPHEN R. PATTON
Corporation Counsel for the City of Chicago

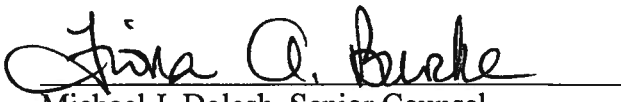
By: 

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EXHIBIT A

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CITY OF CHICAGO,

a municipal corporation,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ACTAVIS PLC; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,

Defendants.

Case No.: 2014L005854
JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT*

Plaintiff City of Chicago, by its attorney, Stephen R. Patton, Corporation Counsel of the City of Chicago, for its Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., the Purdue Frederick Company, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Actavis plc, Actavis, Inc., Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson

*Redacted Pursuant to Confidentiality Agreements

Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively, "Defendants"), alleges as follows:

TABLE OF CONTENTS

I. INTRODUCTION

1. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. When marketing a drug, a pharmaceutical manufacturer must tell the truth, which means ensuring that its marketing claims are supported by science and medical experience. Defendants broke these simple rules.

2. By the 1990s, Defendants had the ability to cheaply produce massive quantities of opium-like painkillers ("opioids"), but the market was small. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. They knew – and had known for years – that opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain (pain lasting three months or longer), particularly because their effectiveness waned with prolonged use and because of the substantial risk of significant side effects and addiction, especially with high-dose use.[1] They also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (e.g., hospitals), where the risk of addiction and other adverse outcomes was much less significant.

3. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[2] Like heroin, prescription opioids work by binding to receptors on the

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[1] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Research & Mgmt., 247-287, (H.L. Fields and J.C. Liebeskind eds., 1994).

[2] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin),

spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and, ultimately, death.

4. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea-change in medical and public perception that would permit the use of opioids for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches. Defendants, through a common, sophisticated, and deeply deceptive marketing campaign that continues to the present, set out to, and did, reverse the popular and medical understanding of opioids.

5. Beginning over 20 years ago, Defendants seized on anecdotal accounts of opioid use to treat chronic pain to begin a reeducation campaign about opioids. They spent millions of dollars funding, assisting, and encouraging doctors and front groups that would pioneer a new and far broader market for their potent and highly addictive drugs – the chronic pain market. Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids. They overstated the benefits of using opioids long-term to treat chronic non-cancer pain, promising improvement in patients' function and quality of life, and dismissed or minimized the serious risks and adverse outcomes of chronic opioid use, including the risk of addiction, overdose, and death. There was and is no reliable scientific evidence supporting Defendants' marketing claims, and there is a

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fentanyl (Duragesic, Fentora), heroin, methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone).

Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II.

wealth of scientific evidence to the contrary. They also deceptively marketed the drugs for indications and benefits that were prohibited by the drugs' labels.

6. Defendants' efforts were wildly successful. The United States is now awash in opioids. In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits result in the prescription of an opioid (nearly double the rate in 2000).[3] Opioids – once a niche drug – are now the most prescribed class of drugs – more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they have consumed 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.[4] Together, opioids generated $8 billion in revenue for drug companies in 2010.

7. Roughly 87% of these prescriptions are for chronic opioid therapy[5] – a prescribing practice doctors previously considered not just ineffective, but even reckless given the substantial risk of addiction chronic opioid use creates.

8. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic." Prescription opioid use contributed to 16,651 overdose deaths nationally in 2010 – more than twice as many deaths as heroin and cocaine combined and surpassing motor vehicle accidents as a cause of death. For every death, more than 30 individuals are treated in the emergency room. The U.S. Department of Health estimated that in 2009 in Chicago, there were

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[3] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51(10) Medical Care, 870-878 (2013).

[4] Laxmaiah Manchikanti et al., *Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective*, 13 Pain Physician, 401-435 (2010).

[5] Michael Von Korff, Group Health Res. Inst., "The Epidemiology of Use of Analgesics for Chronic Pain," Presentation to the FDA (2012), *available at*, http://www.fda.gov/downloads/Drugs/NewsEvents/UCM308128.pdf

40.4 emergency department visits involving adverse reactions to opioids per 100,000 people, which, for Chicago's population, translates into 1,080 trips to the emergency room.[6] But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

9. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors or from the secondary criminal market, and a pipeline of drugs that can be diverted to supply them. Sixty percent of opioid abusers report that their drugs came originally from prescriptions.[7] According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in the past year, and adolescents are abusing opioids in alarming numbers. Sixty percent of opioid abusers report that their drugs came originally from prescriptions.[8] The former president of the New Hope Recovery Center on the City's North Side stated: "Five years ago, 70 percent of the people we saw were heroin addicts. Today, 70 percent of the people we see are prescription drug users."[9]

10. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, which has imposed additional burdens on the City and local agencies that address heroin use and addiction. Chicago ranks first in the nation in heroin overdose deaths.[10] Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost

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[6] *Metro Brief Chicago: Drug-Related Emergency Dep't Visits in Metro. Areas*, U.S. Dep't of Health and Human Servs.: Substance Abuse & Mental Health Servs. Admin. (2009), http://www.samhsa.gov/data/StatesInBrief/2k9/CityReports/Chicago_IL.pdf

[7] Nathaniel Katz, *Opioids After Thousands of Years, Still Getting to Know You*, 23 The Clinical Journal of Pain, 303-306 (2007).

[8] *Id.*

[9] Monifa Thomas, *Prescription Drug Abuse Is Fastest-Growing Drug Problem in Country*, Chicago Sun-Times (Sept. 24, 2012), www.suntimes.com/2989811-417/drug-abuse-prescription-drugs-pain.html.

[10] Natalie Mooer, *Heroin: It's Cheap, It's Available and It's Dangerous Business*, WBEZ 91.5, (Dec. 14, 2013), http://www.wbez.org/news/heroin-its-cheap-its-available-and-its-dangerous-business-109304.

$10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person started on prescription opioids for a back injury, to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

11. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and the former White House drug czar, opines that opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[11]

12. To shift medical convention and unleash this epidemic, Defendants engaged in a campaign of deception that: (1) misrepresented the efficacy of opioids, (2) trivialized or obscured their serious risks and adverse outcomes, and (3) overstated their superiority, compared with other treatments. Defendants supported, encouraged, and directed employees, front groups, and doctors they identified as "Key Opinion Leaders" ("KOLs") to publicize biased and misleading studies and promotional materials and conduct thousands of medical education programs that were deceptive and lacked balance. These "educational" efforts were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors and patients that the benefits of using opioids to treat chronic non-cancer pain outweighed their risks and that opioids could be used safely by most patients.

13. Defendants' representations regarding the benefits, risks, and relative superiority of opioids were – and are – untrue and unsupported by competent scientific evidence. In fact, even Defendants' KOLs initially were very cautious about whether opioids were safe and

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[11] Transcript of Use and Abuse of Prescription Painkillers, The Diane Rehm Show (Apr. 21, 2011), http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript.

effective to treat chronic non-cancer pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers and physicians who have sounded the alarm on the long-term use of opioids to treat chronic non-cancer pain, Defendants continue to disseminate their false and misleading marketing claims even today.

14. Defendants' marketing not only ignored contrary evidence, but also failed to acknowledge risks disclosed on their own labels and sometimes exceeded the approved indications. Defendant Cephalon, for example, marketed its opioid Fentora for chronic non-cancer pain even though it was approved only to treat cancer pain. Defendants also promised that opioids would improve patients' ability to function, even though such benefits had not been proven and were specifically disputed by the FDA.

15. Many of Defendants' strategies are modeled on promotional activities that have been deemed unlawful and for which the drug companies have paid billions of dollars in settlements and judgments. What makes this effort particularly nefarious – and dangerous – is that unlike most other prescription drugs, opioids are highly-addictive controlled substances. Defendants deceptively engaged a patient base that – physically and psychologically – could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

16. Countless Chicagoans suffer from chronic non-cancer pain, which takes an enormous toll on their health, their lives, and their families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived Chicago patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payers of the chance to exercise informed judgment and subjected them to enormous suffering and costs.

17. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Fentora's label) may have allowed or did not exclude the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids; if that were the case, there would be few limits on what a drug company could say about its product.

18. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness, and indeed hijack, what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

19. Defendants' course of conduct, individually and collectively, has violated and continues to violate local, state, and common law, as laid out below.

- Chicago Municipal Code § 2-25-090, in that Defendants engaged in fraudulent, unfair, and deceptive acts and practices, including misleading advertising in their promotion of opioids to treat chronic non-cancer pain, and/or engaged in conduct that violates the Illinois Consumer Fraud and Deceptive Business Practices Act and/or the Uniform Deceptive Trade Practices Act.

- Chicago Municipal Code § 4-276-470 in that Defendants employed deception, fraud, false pretense, false promise or misrepresentation, or concealed, suppressed or omitted material facts with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise.

- Chicago Municipal Code § 1-21-010 in that Defendants knowingly made false statements of material fact to the City in violation of any statute, ordinance or regulation, or knowingly made a false statement of material fact to the city in connection with any application, report, affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit.

- Chicago Municipal Code § 1-22-020, in that Defendants knowingly presented or caused to be presented to the City false or fraudulent claims for payment or approval;

knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the City; and/or conspired to defraud the City by getting false or fraudulent claims allowed or paid.

- Chicago Municipal Code Section § 1-20-020 in that Defendants caused the City or its agents to incur costs in order to provide services reasonably related to Defendants' violation of any federal, state or local law, and/or Defendants failed to correct conditions which violate any federal, state or local law that Defendants were under a legal duty to correct.

- 720 ILCS 5/170-10.5 in that Defendants knowingly obtained, attempted to obtain, or caused to be obtained, by deception, control over the property of a self-insured entity, the City, by making a false claim or by causing a false claim to be made to the City, intending to deprive the City permanently of the use and benefit of that property.

- The common law prohibition against civil conspiracy in that Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

- The prohibition against common law fraud in that Defendants made false statements of material fact that they knew were false to induce the City to act; the City relied on Defendants' false statements, relied on others who relied on Defendants' false statements, or both; and was damaged as a result.

- The common law prohibition on unjust enrichment in that Defendants have unjustly retained a benefit to the City's detriment, and Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

20. To redress and punish these violations, the City seeks a judgment requiring Defendants to pay restitution, damages, including multipliers of damages, disgorgement, civil penalties, punitive damages, and attorneys' fees, costs, and expenses, and any other relief to which the City may be entitled. The City also requests that the Court order Defendants to cease their unlawful promotion of opioids and to correct their misrepresentations.

II. PARTIES

A. Plaintiff

21. Plaintiff is the City of Chicago (the "City"), a municipal corporation organized and existing under the laws of the State of Illinois. The Corporation Counsel has the authority to "[a]ppear for and protect the rights and interests of the city in all actions, suits and proceedings brought by or against it or any city officer, board or department [.]" Chicago Municipal Code § 2-60-020.

B. Defendants

22. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware, Defendant Purdue Pharma Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut, and Defendant The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids, including OxyContin, its largest selling opioid, in both Chicago and the nation. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

23. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million – at the time, one of the largest settlements with a drug company for marketing misconduct. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

24. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Pharmaceutical Industries, Ltd. acquired Cepahlon, Inc. Defendant Cephalon, Inc. is a Delaware corporation with its principal

place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. collectively are referred to herein as "Cephalon.") Cephalon is in the business of manufacturing, selling and distributing pharmaceutical drugs, including opioids Actiq and Fentora, nationally and in Chicago.

25. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain "with malignancies who had developed a tolerance to less dangerous therapies." The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon plead guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

26. Cephalon also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The agreement, *inter alia*, required Cephalon to send doctors a letter advising them of the settlement terms and giving them a means to report questionable conduct of sales representatives; to post payments to doctors on its web site; and to regularly certify that the company has an effective compliance program.

27. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn, was formerly known as Defendant Janssen Pharmaceutica Inc. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and Johnson & Johnson, collectively are referred to herein as "Janssen.") Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in Chicago and nationally, including the opioids Duragesic,

Nucynta, Nucynta ER, Ultracet, and Ultram. Duragesic is the largest selling opioid of the group. Sales of Janssen's opioids collectively commanded between $1.3 billion in revenue in 2009 and $1.2 billion in 2012 – a total of $4.7 billion dollars over the four-year period.

28. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Defendants Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. collectively are referred to herein as "Endo.") Endo develops, markets, and sells prescription drugs, including opioids Opana, Percocet, and Percodan, in Chicago and throughout the United States. These opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana yielded revenue of $1.16 billion between 2008 and 2012, and alone accounted for 10% of Endo's total 2012 revenue.

29. Defendant Actavis plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Defendant Watson Pharmaceuticals, Inc. acquired Defendant Actavis, Inc. in October 2012 and the combined company name was changed to Actavis, Inc. as of January 2013, and then Actavis plc in October 2013. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and is wholly owned by Actavis, Inc. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., now known as Actavis, Inc. Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Throughout the Complaint, "Actavis" collectively refers to Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, and Watson Laboratories, Inc. During the relevant time period, Actavis engaged in the business of marketing and selling opioids in Chicago and across the country, including the branded drug Kadian and generic versions of Duragesic and Opana.

III. JURISDICTION AND VENUE

30. Pursuant to the Illinois Constitution art. VI, § 9, this Court has subject matter jurisdiction over the City's claims.

31. This Court has personal jurisdiction over Defendants pursuant to 735 ILCS § 5/2-209(1) because Plaintiff is the City of Chicago, located within Illinois, and Defendants carry on a continuous and systematic part of their general business within Illinois, and have transacted substantial business in Illinois which has caused harm in Illinois.

32. Venue as to each Defendant is proper in Cook County because, pursuant to 735 ILCS § 5/2-108, part of the transactions out of which the asserted causes of action arise occurred in Cook County, Illinois.

IV. JURY DEMAND

33. Pursuant to 735 ILCS § 5/2-1105, the City demands a trial by jury.

V. FACTUAL ALLEGATIONS

A. Before Defendants' Deceptive Marketing Campaign, Opioids Were Rarely Prescribed by Physicians Because of Their Known Serious Side Effects and Substantial Risk of Addiction

34. Opioids have long been approved and accepted for the treatment of chronic cancer pain. Opioids are appropriate for this use given the severity of pain often associated with cancer and the recognition that the benefits of treating that pain outweigh the potential risk of addiction, especially for terminal patients. The same is not true for chronic non-cancer pain. Among other differences, the pathology responsible for cancer pain is distinct from these pathologies that cause chronic pain. For patients with cancer, the source of their pain is likely to be the tumor and pressure on, or erosion of nerves or bones. Chronic pain arises from multiple sources, including musculoskeletal (from joints, ligaments, or muscles), neuropathic (or nerve-related, occurring in diseases like diabetes or shingles), headache, or functional pain (arising from disease states such as irritable bowel) that respond differently—or not at all—to opioids.

35. However, over the past twenty years, fueled by aggressive marketing from the pharmaceutical industry, opioid use for the management of chronic non-cancer pain has become

commonplace. As set forth below, use of opioids for long-term non-cancer pain management is based on "unsound science and blatant misinformation . . . and dangerous assumptions that opioids are highly effective and safe, and devoid of adverse events when prescribed by physicians."[12]

36. As admitted in 1994 by Dr. Russell Portenoy, a KOL who went on to tirelessly promote opioid therapy for the treatment of chronic non-cancer pain (also called chronic nonmalignant pain), the medical consensus before Defendants' "reeducation" campaign was decidedly against the use of opioids to treat chronic non-cancer pain:

> ***The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs.*** This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. ***Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects.*** There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.[13]

37. Dr. Portenoy left no doubt about the 1994 state of knowledge concerning the safety and efficacy of opioid therapy for long-term chronic non-cancer pain:

> At the present time, neither the medical literature nor clinical experience provides compelling evidence that long-term opioid use would be salutary for more than a very small number of patients with chronic nonmalignant pain . . .[14]

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[12] Laxmaiah Manchikanti et al., *Opioid Epidemic in the United States*, 15(3 Suppl) Pain Physician, ES9-ES38 (July 2012).

[13] Portenoy, *supra* note 1, at 247 (emphasis added).

[14] *Id.* at 278 (emphasis added).

38. But the lack of any credible science supporting opioid therapy for chronic non-cancer pain did not stop Defendants from marketing opioid therapy for that use. Working with and through KOLs like Dr. Portenoy, Defendants seized on anecdotal accounts of opioid efficacy in limited populations and methodically, through numerous publications, programs, and spokespeople, overstated the benefits and understated the risks of opioids in order to create and defend a broad market for opioids that never should have and never would have come to exist absent Defendants' concerted, deliberate, and patently misleading efforts.

B. Defendants Are Obligated to Ensure that their Marketing is Truthful, Complete, and Balanced

39. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. Drug makers' claims in promotional materials must be supported by "substantial" scientific evidence and cannot be false or misleading. 21 U.S.C. § 352(a). The materials must reflect a "fair balance," accurately and comprehensively describing the risks and benefits of the drug, and cannot ignore or minimize a drug's risk or overstate its benefits. 21 CFR § 202.1(e)(6). Federal regulations bar affirmative claims that are untruthful, as well as the omission of material facts that make the drug-related information inaccurate. 21 CFR §§ 202.1(e)(3), 1.21(a). It is a violation of federal law for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study." 21 CFR § 99.101(a)(4).

40. Drug companies also must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience." 21 CFR § 202.1(e)(6)(ii). While the FDA must approve a drug's label — defined to include all explanatory material accompanying the label, 21 U.S.C. §§ 321 (k), (m) — it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information. *See*

21 CFR § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 CFR § 314.70(c)(2) (allowing manufacturers to make changes that "strengthen . . .a warning, precaution, or adverse reaction). In addition, while promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated, the FDA does not have to approve these materials in advance. If, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations that it deems less serious, while warning letters are reserved for violations that affect patients' safety or reflect continued violations of the law.

41. The federal regulatory framework reflects public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for making certain that prescribers have accurate and complete information so that they can assess the risks and benefits of drugs for their patients to ensure their health and safety. The Chicago Consumer Fraud and False Claim ordinances reflect the same judgment that drug companies, like other businesses, have a duty to deal honestly with consumers, government, and other payers who purchase and use their products.

C. Defendants' Marketing of Opioids for Long-Term Use to Treat Chronic Non-Cancer Pain was False, Misleading, Imbalanced, and Unsupported by Science

42. For years, Defendants systematically violated state and local laws requiring that the promotion of pharmaceutical drugs, like other consumer products, not be false, deceptive, or misleading. Defendants manipulated and ignored scientific evidence to formulate and broadcast the misrepresentations described below, each of which was instrumental in: (1) overcoming longstanding medical and legal barriers to opioid therapy for chronic non-cancer pain; and (2) making high-dose, long-term opioid use the new "gold standard" of treatment of chronic non-cancer pain.

43. Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unbranded marketing materials—materials that generally promoted opioid use but did not name a specific opioid drug name. Upon information and belief, Defendants used these unbranded materials, which are not reviewed by the FDA, to disseminate messages that were inaccurate, were inconsistent with their branded marketing materials and the drugs' labels and package inserts, and would not pass muster with the FDA. Had they relied on branded materials, the FDA-required drug labels and package inserts would have been included to more fully describe the risks and administration of opioids.

44. Defendants marketed directly to patients to: (1) encourage them to ask doctors for opioids to relieve chronic non-cancer pain; and (2) allay their well-founded concerns that opioids were dangerous and addictive. Defendants targeted particularly vulnerable, but usually well-insured, groups of patients, such as veterans and the elderly. Defendants leveraged and funded patient organizations and communities – promoting opioids particularly for common conditions, such as headaches, arthritis, fibromyalgia, and back pain. Unlike other direct-to-consumer marketing, Defendants, as a group, focused on unbranded advertising knowing that the creation of a new, expansive market for opioids would benefit all manufacturers.

45. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic non-cancer pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Through misleading medical education programs, treatment guidelines, and other efforts, Defendants "reeducated" general practitioners and family doctors. They knew that these doctors reach the vast majority of patients with common chronic pain complaints, but are less likely than specialists to have the time or knowledge to evaluate Defendants' deceptive messages or to closely monitor patients for signs of improvement or adverse outcomes (such as addiction).

46. Individually and collectively, Defendants developed, disseminated and promoted a series of misrepresentations aimed broadly at reversing the ultimately well-founded fears and beliefs of doctors and patients.

1. Defendants' misrepresentations regarding the benefits of opioids for chronic non-cancer pain.

47. Defendants deceptively promoted opioids as improving chronic non-cancer patients' function by allowing them to get back to "normal" and reducing their pain long-term. Defendants misrepresented the efficacy of opioids in an effort to persuade doctors and patients that their benefits outweigh their risks.

48. Although opioids may initially improve patients' function by providing pain relief in the short term, there were – and are – no controlled studies of the use of opioids beyond 16 weeks and no evidence that opioids improve patients' function long-term. Indeed, research such as a 2008 study in *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[15] Despite this lack of evidence — and evidence to the contrary — Defendants consistently promoted opioids as capable of improving patients' function and quality of life.

49. The FDA has recognized that claims that opioids improve patients' function are misleading. For example, a company claimed that its opioid "Improved Overall Function," offered "Long Lasting Improvements in Physical Function," and would enable patients to be better able to engage in a list of daily activities, such as walking, standing, and climbing stairs. In a warning letter sent March 24, 2008, the FDA publicly made clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities … has not been demonstrated by substantial evidence or substantial clinical experience."

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[15] Jeffrey Dersh et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine, 2219-2227 (Sept. 15, 2008).

50. In marketing Kadian, Actavis made implied claims that the drug would allow chronic non-cancer pain patients to return to work, relieve "stress on your body and your mental health," and help them enjoy their lives. The FDA found that Actavis misrepresented the scientific evidence: "[W]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[16]

51. Defendant Janssen also distributed a series of posters to doctors' offices that showed pictures of people dressed for a variety of active professions suggesting that doctors prescribe Ultracet because "Pain doesn't fit into their schedules." Despite the lack of scientific evidence in support of such a claim, the posters falsely implied that Ultracet was appropriate for help in maintaining an active lifestyle. Several of the posters contained the tagline "Ultracet lets them perform."

52. In spite of the complete lack of scientific basis, in 2011, Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, published by the American Pain Foundation ("APF"), which asserted that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic non-cancer pain patients. To support this claim, APF cited *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, a study published in 2006 in the Canadian Medical Association Journal. However, the study concludes: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The Purdue-sponsored *Guide* failed to disclose this conclusion, as well as the fact that the study was conducted only for five weeks, and therefore could not support the long-term use of opioids, or the study's findings that opioids were actually less effective than alternative treatments.

[16] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18. 2010).

53. [redacted] In 2009, one of its marquee components was a "first-of-its-kind" Web-based series, called *Let's Talk Pain,* hosted by veteran TV journalist Carol Martin. [redacted]

54. The *Let's Talk Pain* talk show—which is still available online—[redacted] In the very first episode of this talk show, the following exchange, from a script edited and approved by Janssen, took place:

> **Teresa Shaffer (APF Action Network Leader)**: As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> **Dr. Al Anderson (AAPM Board of Directors)**: The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor when they are suffering from pain for a long period of time, especially moderate to severe pain. And that's the patients that we really need to use the opioids methods of treatment, because they are the ones who need to have some help with the function and they're the ones who need to have their pain controlled enough so that they can increase their quality of life.

> **Teresa Shaffer**: This is what has allowed me to continue to function and is what has allowed me to have somewhat of a normal life, is the opioids.[17]

There simply is no scientific evidence that opioids taken long-term improve function or quality of life for chronic non-cancer pain patients, and significant evidence that opioids impose significant risks and adverse outcomes on long-term users, none of which is disclosed in this video interview.

55. Similarly, the National Initiative on Pain Control ("NIPC"), an APF initiative [redacted] ran a facially unaffiliated website called www.painknowledge.org. NIPC billed itself as "an integrated education initiative" and promoted its expert leadership team, including "nationally respected experts in the pain management field." [redacted] Painknowledge.org promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy.

56. Endo also advertised its Opana ER (or extended release) drug by depicting a professional chef and a construction worker, each with chronic lower back pain, smiling and working as a result of Opana ER.

57. [redacted]

58. Defendants' misrepresentations about increased function are particularly misleading for specific indications for which they promoted opioids, such as migraines and lower back pain. For instance, research indicates that as many as 30% of patients who suffer from

[17] Let's Talk Pain, *Episode 1: Safe Use of Opioids (PainSAFE)*, YouTube (Sept. 28, 2010), http://www.youtube.com/watch?v=zeAlVAMRgsk (0:35 to 1:09).

migraines have used opioids to treat their headaches.[18] Despite this, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.[19] A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[20] Studies of the use of opioids long-term for chronic lower back pain similarly have been unable to demonstrate an improvement in patients' function.[21]

59. There also is evidence that, over the long-term, opioid therapy fails to lessen, and sometimes increases, patients' pain – important facts that Defendants fail to include in their marketing literature. For example, Defendants have failed to disclose scientific evidence that establishes that many patients on chronic opioid therapy continue to experience significant pain and dysfunction.[22] Defendants also have failed to disclose research and clinical experience demonstrating that: (1) the analgesic (pain relieving) efficacy of opioids often declines over time; (2) patients on opioids long-term may develop greater sensitivity to pain ("hyperalgesia");

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[18] Dawn C. Buse, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, 52 Headache: The Journal of Head & Face Pain, 18-36 (Jan. 2012).

[19] *Id.*

[20] *Press Kits – Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment*, National Headache Foundation (May 15, 2007), http://www.headaches.org/press/NHF_Press_Kits/Press_Kits_-_Migraine_Patients_Taking_Addictive_Or_Non_Approved_FDA_Migraine_Treatments.

[21] Luis E. Chaparro, *Opioids compared to placebo or other treatments for chronic low-back pain*, 8 Cochrane Database of Systematic Reviews (2013).

[22] Mark D. Sullivan et al., *Problems and concerns of patients receiving chronic opioid therapy for chronic non-cancer pain*, 149(2) Pain, 345-353 (2010); Jørgen Erikson et al., *Critical issues on opioids in chronic non-cancer pain*, 125(1-2) Pain, 172-179 (2006); *see also*, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*, Institute of Med. Comm. on Advancing Pain Research, Care, & Educ. Board on Health Sci. Policy, (2011). K.S. Dillie et al., *Quality of life associated with daily opioid therapy in a primary care chronic pain sample*, 21(2) Journal of the Am. Bd. Of Family Med., 108-117 (Mar.-Apr., 2008).

and (3) because they develop tolerance to the medication over time, many chronic non-cancer pain patients require ever higher doses of opioids to obtain relief and are on doses that doctors have described as "frighteningly high."[23]

60. Consistently, in their marketing, Defendants failed to disclose the lack of evidence to establish that opioids are safe and effective long-term, as well as the growing body of evidence that the risks of opioids increase and their benefits decline over time. The studies relied on by Defendants in marketing their drugs are short-term, typically for less than 12 weeks. For example, an ad that Janssen currently is running, including on its website, claims that Nucynta ER has "Efficacy you need, Tolerability you want." However, each of the studies included in the drugs approval were only conducted over a 12-week period, using a pre-seeded patient group; thus none provide support for a claim of long-term efficacy in the population at large. Indeed, Janssen also failed to disclose that it submitted a fourth study for the FDA's consideration that did not show pain reduction over placebo and was thus omitted from the approval.

61. As a pain specialist noted in an article titled, *Are We Making Pain Patients Worse?*, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." Instead, at higher doses, patients are much more likely to develop dependence or addiction, experience pain deterioration due to hyperalgesia, and are three to nine times more likely to die from opioid-related causes than those on low doses.[24] Additionally,

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[23] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med., 1422-1424 (Sept. 13, 2010).

[24] Tara Gomes et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain*, 171(17) Archives of Internal Med., 686-691 (Apr. 11, 2011); Kate M. Dunn et al. *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med., 85-92 (Jan. 19, 2010).Most overdoses were medically serious and 12% were fatal. *Id. See also* J.B. Braden et al., *Emergency Department visits among recipients of chronic opioid therapy*, 170(16) Archives of Internal Med., 1425-1432 (Sept. 13, 2010) (finding that higher doses of opioids doubled the risk of adverse drug events).

epidemiological data suggest that only a minority of patients on chronic opioid therapy benefit from the drugs and most continue to suffer significant pain and limitations on their activities. Defendants have never disclosed these facts.

2. Defendants' misrepresentations regarding the adverse outcomes and risks of opioids.

62. In an effort to persuade doctors to prescribe opioids for chronic non-cancer pain, Defendants deceptively overstated the safety and minimized the adverse outcomes, particularly the risk of addiction and abuse from using opioids long-term.

a. Risk of addiction and abuse.

63. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic non-cancer pain patients, Defendants had to overcome doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk – condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic non-cancer pain conditions sufficient to justify that risk would have posed a nearly insurmountable challenge.

64. Remarkably, Defendants were able to do it; even though opioids are controlled substances – classified under the federal Controlled Substances Act as having "high potential for abuse" and a "risk of severe psychological and physical dependence."[25] Defendants: (1) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (2) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk – and Defendants' own FDA labels – compelled disclosure.

[25] 21 U.S.C. § 812(b).

65. Contrary to Defendants' claims, numerous studies support that, though these patients may not presently show signs of abuse or addiction, at least 15% and as many as 40% of patients will become addicted to opioids.[26] Research has shown that opioids are even more addictive than cocaine and alcohol. One in three to five users who self-administer short-acting opioids will become addicted, versus one in eight to fifteen for users of cocaine or alcohol.[27]

(1) Minimizing the risk of addiction.

66. Local pain specialists interviewed by the City indicated that sales representatives, or detailers, employed by drug companies, never talked to them about the risk of addiction from long-term use of opioids.

67. Nor did their marketing materials portray the risk of abuse or addiction. As discussed below, Defendants omitted addiction from the list of adverse outcomes they disclosed. In addition, to the extent they discussed addiction, they described it as "rare" or not an issue for pain patients, as opposed to illicit users.

68. For example, in a Janssen- sponsored publication, *Finding Relief: Pain Management for Older Adults,* published in 2009 and still available online, Janssen asserts as "Fact" that "opioids are *rarely* addictive when used properly for the management of chronic pain." (Emphasis in the original.) [redacted]

[26] (*E.g.*, Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction, 1776-1782 (Oct. 2010); Joseph A. Boscarino et al., *Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria*, 30(3) Journal of Addictive Diseases, 185-194 (July-Sept., 2011); *Prescription Drugs: Abuse and Addiction,* National Inst. on Drug Abuse, (Oct. 2011), http://www.drugabuse.gov/sites/default/files/rrprescription.pdf.)

[27] Mary J. Kreek et al., *Pharmacotherapy of Addictions*, 1(9) Nature Reviews: Drug Discovery, 710-726 (Sept. 2002).

69. Similarly, Endo promised on a website it funded, that "People who take opioids as prescribed usually do not become addicted."

70. Defendants' efforts to minimize the risk of addiction from taking opioids long-term are evident in the contrast between their unbranded materials, which dramatically understate or deny the risk of addiction, and branded materials, which include stronger addiction warnings taken from the drugs' labels. Defendants took advantage of the less-monitored unbranded marketing channel to disseminate their deceptive messages regarding the risk of addiction from long-term opioid use. For example (emphasis added):

		Opana ER Advertisement (2011/2012/2013)
		branded Endo advertisement
		"[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit." "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use."**

71. Defendants also falsely reassured doctors and patients that, when taken properly under a doctor's supervision, opioids would not become addictive. Defendants' representations that opioid addiction can be effectively managed by competent physicians not only had the effect of increasing the number of opioid prescriptions, but deflected the responsibility from Defendants' marketing to doctors' prescribing and treatment practices.

72. Defendants deceptively downplayed the risk of addiction for chronic pain patients by defining opioid addicts as people who get the drugs illicitly and take them improperly – not

patients taking drugs they were prescribed. According to Defendants, patients who take opioids prescribed to them are not addicted.

73. A 2004 Endo patient education publication, edited by KOL Dr. Russell Portenoy, and titled, *Understanding Your Pain: Taking Oral Opioid Analgesics*, which is still available online, answers the hypothetical patient question — "What should I know about opioids and addiction?" — by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that, "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction."

74. [redacted]

75. More graphically, a Purdue brochure, still provided to doctors today, called *Indications of Possible Drug Abuse*; shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, or perforated nasal septa.[28] In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassure doctors that as long as they did not observe those signs, they need not worry that their patients were abusing or addicted to opioids.

76. These deceptive messages gave doctors and patients a false sense of security that as long as patients are only taking opioids a doctor gives them – regardless of the dose or frequency ingested– and not manipulating them, snorting, or injecting them, they are not addicted. That is dangerously false Many opioid users who become addicted to the drugs began using them when a doctor prescribed them. Pain patients and opioid addicts are not separate

[28] *Providing Relief, Preventing Abuse: A reference guide to controlled substance prescribing practices*, Purdue Pharma L.P. (Stamford, C.T.), 2nd ed. 2011, at 13.

universes, but overlapping circles. As one study noted, "a potential side effect from chronic use can be abuse and addiction … [I]n fact, correct use and abuse of these agents are not polar opposites – they are complex, inter-related phenomena."[29] A review of studies of urine drug monitoring for opioid patients showed that at least 11% of patients with chronic non-cancer pain were misusing opioids and at least 12% were not taking their medication as prescribed.[30]

77. Dr. Scott Fishman, another KOL whose work was long supported by opioid makers, acknowledged that data supporting the contention that addiction is rare:

> [The data] have been found to be inadequate and seriously flawed. Although we currently do not know the exact rate of addiction in patients legitimately prescribed opioids for pain or the rate of overall misuse, we know that rates are high enough that they should be considered a significant potential adverse effect.[31]

78. Relatedly, at least Endo, and potentially other Defendants, sought to minimize the risk of abuse by misrepresenting their drugs' susceptibility to tampering. In 2012, Endo asked the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, meaning that it was protected against manipulation that would allow users to snort or inject it. It also sought permission to withdraw its previous approval for Opana ER in favor of its newer, purportedly safer version. The FDA denied both requests, explaining in a May 10, 2013 letter that there was no evidence the new design "would provide a reduction in oral, intranasal or intravenous abuse" and that Endo's "postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse[.]" Yet, Endo advertised, and advised its sales representatives and speakers' bureau doctors, to market reformulated Opana ER as "the only oxymorphone extended release tablets that are *designed to be crush resistant*."

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[29] Wilson M. Compton & Nora D. Volkow, *Major increases in opioid analgesic abuse in the United States: concerns and strategies*, 81(2) Drug and Alcohol Dependence 103, 106 (Feb. 1, 2006).

[30] Nathaniel P. Katz et al., *Prescription Opioid Abuse: Challenges & Opportunities for Payers*, 19(4) Am. Journal of Managed Care 295, 301 (2013).

[31] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide*, 15, The Fed'n of State Med. Bds. Found., 2nd ed. (2012).

(Emphasis added.) Endo chose its words carefully, but the misleading impression it created – that Opana is tamper-resistant and therefore less subject to abuse – was no doubt deliberate.

(2) Claiming the risk of addiction can be identified and managed.

79. Defendants continue to maintain to this day that *most* patients safely can take opioids long-term for chronic non-cancer pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, Defendants have come to admit that *some* patients *could* become addicted. But, more recently, Defendants claim that opioid addiction can be avoided if doctors use screening tools or questionnaires that identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse).[32]

80. There are three fundamental flaws in Defendants' assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to substantially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients can be given opioids safely, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients without red flags can take opioids long-term without significant danger of addiction.

81. Yet Defendants made assurances about addiction and screening anyway. [redacted]

82. Dr. Russell Portenoy, a pro-opioid, Defendant-funded KOL, appeared on *Good Morning America*, in 2010, to discuss the use of opioids long-term to treat chronic non-cancer pain. He claimed that, "[a]ddiction, when treating pain, is distinctly uncommon. If a person

[32] The FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics directs doctors to "assess each patients' risk of abuse." However, it does not excuse drug companies' misrepresentations that the screening tools allow them to prevent low-risk or high-risk patients from abusing or becoming addicted to opioids.

does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

83. A Cephalon-sponsored guide, *Opioid Medications and REMS: A Patient's Guide*, similarly claimed: "Some people are nervous about taking opioids because they are afraid they will become addicted. However, patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

84. Pro-opioid KOL Lynn Webster developed a basic five-question risk screening tool called the Opioid Risk Tool. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to doctors in Chicago during the relevant period.

85. An Endo-sponsored 2007 supplement to the *Journal of Family Practice* contained an article written by a Chicago doctor who was on all of Defendants' speakers' bureaus, *Pain Management Dilemmas in Primary Care: Use of Opioids*, which recommended risk screening through the use of the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain. The author claimed that even patients at high risk of addiction could be safely treated with opioids through "a maximally structured approach" including toxicology screens and pill counts.

86. In 2012, the same Chicago KOL also presented at a Purdue-sponsored continuing medical education program ("CME"), *Chronic Pain Managing and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, in which he discussed the treatment of a high-risk chronic pain patient demonstrating signs of opioid addiction. The presentation recommended that doctors facing a similar patient, again, use risk screening tools. He also taught that doctors should consider reducing the prescription fills and switching to a different opioid as management strategies. Regardless of steps taken, the message was to continue opioid therapy.

87. Many of Defendants' misrepresentations about opioid abuse and addiction risk were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions, but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. Defendants have made a concerted effort to reach GPs through continuing medical education programs ("CMEs"), office visits, and literature specifically aimed at them, and most opioids are prescribed by primary care physicians like GPs.[33]

88. Defendants organized CMEs for GPs on prescribing opioids to chronic pain patients, but provided no guidance on recognizing opioid abuse or weaning patients off opioids. Since GPs lack specialized training in opioid treatment and are especially reliant on CMEs to equip them to manage patients on opioids, this critical learning gap makes it even less likely that, once on opioids, chronic pain patients will have the chance to get off them.

(3) Deflecting attention to "undertreated" pain.

89. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. They claimed that purportedly overblown worries about addiction caused pain to be under-treated and opioids to be over-regulated and under-prescribed. One APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, stated that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include … misconceptions about opioid addiction." The Purdue Guide further alleged that resulting regulatory constraints (like the FDA's recently mandated prescriber education program, or REMS ("Risk Evaluation and

[33] Wolters Kluwer Health, *Sharp rise in opioid drugs prescribed for non-cancer pain*, Science Daily (Sept. 16, 2013), available at http://www.sciencedaily.com/releases/2013/09/130916091218.htm.

Mitigation Strategies") have a "chilling effect" on prescribing and that abuse of opioids injured and "jeopardize[d] effective pain management by impeding patient access to opioids."

90. [redacted]

91. A Purdue website called *In the Face of Pain* complained, under the heading of "Protecting Access," that, through at least mid-2013, policy governing the prescribing of opioids was "at odds with" best medical practices by "unduly restricting the amounts that can be prescribed and dispensed;" "restricting access to patients with pain who also have a history of substance abuse;" and "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe."[34] This unsupported and untrue rhetoric aimed to portray doctors who did not prescribe opioids as uncaring, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

(4) Physical dependence vs. addiction.

92. In an effort to underplay the risk and impact of addiction, Defendants frequently claim that while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed by gradually tapering patients' dosage to avoid the adverse effects of withdrawal.

93. For example, in the April 2, 2010 version of its OxyContin label, Purdue states: "**Cessation of Therapy** When the patient no longer requires therapy with OxyContin, taper the

[34] *See In the Face of Pain Fact Sheet: Providing Access to Pain Treatment*, Purdue Pharma L.P. (2013), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf

dose gradually to prevent signs and symptoms of withdrawal in the physically-dependent patient." The APF *Policymaker's Guide* (2011) funded by Purdue states: "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation."[35] [redacted]

94. Defendants' so-called guidance overstates the ease of withdrawing from long term use of opioids and the adverse effects that accompany their discontinuance. Withdrawal from opioids after long-term use can trigger severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms. The dependence on opioids can be so severe that withdrawal symptoms may persist for months, or even years, after a complete withdrawal from opioids.

95. Defendants also fail to disclose that long-term opioid use often causes psychological, as well as physical, dependence. Addiction is not a switch that is either off or on. Indeed, as the most recent, authoritative Diagnostic and Statistical Manual of Mental Disorders ("DSM-V") acknowledges, there is a spectrum of disorders that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on that spectrum. [36]

96. This is certainly true of opioids. Anxiety over ending opioid use can trigger cravings for opioids, even after a patient is no longer physically dependent and despite the fact that he or she is not deriving benefits from the treatment. As Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, explains, opioids

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[35] *A Policymaker's Guide to Understanding Pain & Its Mgmt.*, Am. Pain Found., Oct. 2011 at 31.

[36] For that reason, references to "addiction" in this Complaint refer to this spectrum of substance abuse disorders.

"hijack[] the brain's reward system," convincing users that "the drug is needed to stay alive."[37] Even absent physical dependence, a patient's fear of the unpleasant effects of discontinuing opioids can cause patients to seek the drugs.[38]

97. Thus, ending opioid therapy is not, as Defendants claim, "simply" a matter of gradually lowering a patient's dosage over time. In fact, one of the significant risks in beginning chronic opioid therapy is that, once patients become physically dependent, it will be difficult for them to ever stop using opioids. According to one study, more than half of patients who continuously use opioids for more than 90 days remain on opioids after more than five years.[39] Most patients who become physically dependent after long term use will require opioid maintenance (through methadone or buprenorphine) for years or decades. Defendants fail to disclose this significant risk to doctors and patients.

98. A publication in Purdue's current catalog of publications for providers, *Providing Relief, Preventing Abuse*, cautions against the "common error" of confusing physical dependence with addiction. It analogizes physical dependence on opioids to physical dependence on antihypertensives (blood pressure medicine) or decongestants.

99. This analogy has no basis in fact. With non-addictive drugs, like blood pressure medicine, patients may experience withdrawal symptoms, but they are rarely difficult to get over, and there is no craving for the drug. However, with long-term use of opioids, even in the absence of a formal diagnosis of addiction, patients often crave the drug long after they have discontinued use. Patients on opioids long-term will often experience symptoms that arguably may not qualify as full-blown addiction, but are certainly not mere physical dependence.

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[37] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Register (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

[38] Jane C. Ballantyne & Cathy Stannard, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids*, 21(5) Pain: Clinical Updates, 1-7 (Dec. 2013).

[39] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) Journal of Gen. Internal Med., 1450-1457 (Dec. 2011).

Defendants' marketing failed to acknowledge the spectrum of substance abuse disorders short of full blown addiction, which also are cause for concern, and created the sense that doctors need only concern themselves with signs of addiction.

100. As with the claimed low incidence of addiction, the misrepresentation that chronic opioid therapy is easy to stop is important to Defendants' fraudulent marketing scheme. Honestly describing the difficulty of removing patients from opioids after long-term use and the complexity of patients' dependence would rebalance the risk-benefit analysis and stoke doctors' and patients' well-grounded concerns that once on opioids, severe physical and psychological dependence would make it extremely difficult for patients to ever stop their use. It might also motivate the general practitioners to whom Defendants generally marketed opioids for long-term use to refer patients requesting opioids to pain management specialists who would not so easily prescribe them. Defendants also gave GPs a false sense of confidence that they could identify addiction, distinct from physical dependence, which, again, allowed them to believe that they could continue to responsibly prescribe opioids. Defendants chose not to tell the truth so that they could sell more drugs.

(5) Pseudoaddiction.

101. Defendants needed a way to explain why so many chronic non-cancer pain patients on opioids seem to be addicted: they ask for drugs by name, they seek refills earlier than their supplies should have run out, hoard drugs, or self-escalate their doses. Defendants, led by Purdue, managed masterfully to turn these recognized signs of addiction into a way to sell more opioids through the concept of "pseudoaddiction." Pseudoaddiction, which manifested with all of the signs of addiction, was actually the result of insufficient opioids to treat pain, and should be treated with higher or more frequent doses of the drugs. Defendants claimed that rather than addiction treatment, patients who were pseudoaddicts needed more opioids.

102. Purdue discussed pseudoaddiction in a publication called *Providing Relief, Preventing Abuse*, in which it falsely and misleadingly claimed that the concept of

pseudoaddiction had "emerged in the literature" "to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." Purdue went even farther, saying that pseudoaddiction is unproblematic and may occur "occasionally even with successful opioid therapy for pain." This gave doctors confidence that signs of addiction might not be cause for concern. It also misled doctors into believing that the proper response to pain that has not been "effectively treated" through opioid prescriptions is *more* opioids. Purdue's unbranded website, Partners Against Pain.com, also hosted a pamphlet in 2005 titled, *Clinical Issues in Opioid Prescribing*, which included a list of conduct including "illicit drug use and deception" as examples of unproblematic pseudoaddiction-related behavior, not problematic addiction.

103. Defendants also managed to work the misleading concept of pseudoaddiction into medical literature. In a 1994 article, Defendant-sponsored KOL Russell Portenoy described common signs of addiction as potential signs of mere *therapeutic dependence* – which he likened to a diabetic's response to insulin – or *pseudoaddiction*.[40] Portenoy claimed that "*Pseudoaddiction* describes a specific phenomenon that has also been observed in the population with cancer pain." But his authority for this statement was limited to a single citation to an article by another KOL and later Purdue executive J. David Haddox.[41] Dr. Haddox's article did not concern a population study at all, but rather, simply reported the possible phenomenon in a single cancer (leukemia) patient with pneumonia and chest wall pain.[42]

104. Dr. Portenoy took the deception of pseudoaddiction one step farther, separating from a list of commonly accepted signs of drug addiction those he claimed were "probably less predictive of addiction."[43] Portenoy's "less predictive of addiction" list included:

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[40] Portenoy, *supra* note 1, at 266-267.

[41] *Id.* at 267.

[42] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) Pain, 363-366 (Mar. 1989).

[43] Portenoy, *supra* note 1, at 267 Table III.

i. Aggressive complaining about the need for more drugs;

ii. Drug hoarding during periods of reduced symptoms;

iii. Requesting specific drugs;

iv. Openly acquiring similar drugs from other medical sources;

v. Unsanctioned dose escalation or other noncompliance with therapy on one or two occasions;

vi. Unapproved use of the drug to treat other symptoms;

vii. Reporting psychic effects not intended by the clinician; and

viii. Resistance to a change in therapy associated with 'tolerable' adverse effects with expressions of anxiety related to the return of severe symptoms.

105. Portenoy cited no authority for his "less predictive of addiction" conclusion and is not himself a specialist or authority in addiction medicine. Yet his list encouraged doctors to ignore obvious signs of addiction and prescribe more opioids.

106. Similarly, in his book, *Responsible Opioid Prescribing* (2007), which was funded by Defendants Cephalon, and Purdue, and is still distributed in Chicago, Dr. Scott Fishman asserts: "It may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications. But other causes of non-adherence should be considered before a judgment is made." Thus, according to Defendants, even patients at high risk for opioid addiction should be given the benefit of the doubt (and more opioids).

107. Defendants' used identical language to describe pseudoaddiction in their materials, evidence of their common efforts and messages (emphasis added):

Let's Talk Pain **(2009)**	***A Policymaker's Guide*** **(2011)**	***Clinical Issues in Opioid Prescribing*** **(2005)**
funded by Janssen	funded by Purdue	funded by Purdue
"A related term is pseudoaddiction, which refers to patient behaviors that may occur when **pain is under-treated** . . . Pseudoaddiction is **different from true addiction** because such behaviors can be resolved	"Pseudo-addiction describes patient behaviors that may occur when **pain is undertreated** . . . Pseudo-addiction can be **distinguished from true add[i]ction** in that this behavior ceases when pain is effectively	"Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when **pain is undertreated** . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief.

with effective pain management."	treated."	Pseudoaddiction can be **distinguished from true addition** in that the behaviors resolve when the pain is effectively treated."

108. Despite Defendants' claims, pseudoaddiction has no scientific basis; there is no competent study documenting its existence. Based on a single cancer pain case observed by Purdue executive and KOL David Haddox, Defendants have counseled doctors to treat chronic non-cancer pain patients on opioids who seem to be addicted *with more opioids*.

109. KOL Dr. Lynn Webster recommended just this course in his book, *Avoiding Opioid Abuse While Managing Pain* (2007), [redacted] Dr. Webster advised giving patients more medication when unsure whether a patient is showing signs of addiction or untreated pain; he asserted that pseudoaddiction was the cause *"in most cases and should be the clinician's first response*." Lynn R. Webster, Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007) (emphasis added). Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication.... It led us down a path that caused harm. It is already something we are debunking as a concept."[44]

(1) Other adverse effects.

110. Defendants also misrepresent the risks of long-term opioid use by describing them as minor and short-term and failing to disclose the most significant risks. Defendants most frequently highlight the risk of constipation, which they advise can be addressed with laxatives

[44] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee-Wisconsin Journal Sentinel (Feb. 18, 2012), http://www.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.[45] H. W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3(5) The Journal of Pain, 377-384 (Oct. 2002)Nathaniel Katz & Norman A. Mazer, *Impact of opioids on the endocrine system*, 25 The Clinical Journal of Pain, 170-175 (2009).

or other treatments. The other side effects Defendants typically disclose are drowsiness, nausea and vomiting, mental clouding (sometimes disclosed), and itching, though Defendants promise that these symptoms will go away in a matter of days.

111. Below is a representative example of how Defendants disclose potential side effects from opioid use in unbranded material. This is taken from a 2009 patient education publication distributed by the NIPC and funded by Endo, and which was distributed in Chicago during the last four years:

> **As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:**
>
> - Constipation
> - Drowsiness
> - Confusion
> - Nausea
> - Itching
> - Dizziness
> - Shortness of breath
>
> Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

112. Notably absent from this list are far more significant adverse outcomes linked to long-term opioid use, including: hyperalgesia, immunologic and hormonal dysfunction, respiratory depression, apnea, tolerance/loss of analgesic efficacy, endocrinopathies (most notably testosterone depletion, which, among other impacts, may decrease pain tolerance and the effectiveness of opioids),[45] cognitive impairment, dependence, and addiction. These adverse outcomes can result in an increase in falls and fractures in the elderly (which can shorten the

[45] H. W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3(5) The Journal of Pain, 377-384 (Oct. 2002)Nathaniel Katz & Norman A. Mazer, *Impact of opioids on the endocrine system*, 25 The Clinical Journal of Pain, 170-175 (2009).

lives of elderly patients), overuse, overdose, and death. Defendants also fail to disclose the risk that infants born to pregnant women using opioids will be dependent on opioids as well, suffering a condition called neonatal abstinence syndrome when they painfully withdraw from the drug after birth.[46] In addition, though the labels for opioids contain numerous warnings about use of opioids for patients who have certain conditions, are opioid naïve (new to opioids), or use other drugs, Defendants' marketing materials contain no similar cautions.

113. These omitted adverse outcomes are not, as Defendants claim, fleeting or minor. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic non-cancer pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[47] Defendants were aware of this high drop-out rate as they pushed the FDA to allow them to exclude these patients from clinical trial data, a method of research known as "enriched enrollment," which allowed drug companies to study only those patients whose negative reactions to opioids did not cause them to stop taking them.

114. Janssen's marketing campaign for Nucynta was particularly deceptive in that it promoted Nucynta's "tolerability," which is completely at odds with and misrepresents its serious side effects. In October 2009, Janssen began to run an advertisement in *Medical Economics* that proclaimed: "OPIOID EFFICACY MEETS UNEXPECTED TOLERABILITY," even though the risk of addiction and serious side effects make opioids intolerable for most patients. While the "tolerability" to which Janssen referred was a lack of GI-related side effects (*e.g.*, nausea and vomiting), a reader could only learn this after examining a bar chart representing the study's results. Thus, the all-caps claim of "unexpected tolerability" falsely implied that Nucynta could be taken without severe side effects or consequences.

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[46] The FDA now requires a boxed warning on all extended release and long acting opioids, cautioning that chronic use of those drugs by pregnant women can result in neonatal opioid withdrawal syndrome ("NOWS"), which may be life-threatening and require specialized care.

[47] Meredith Noble et al., *Long-term opioid management for chronic noncancer pain (Review)*, 1 Cochrane Database of Systematic Reviews, (2010).

115. Defendants' misleading treatment of the serious risks of opioid treatment in unbranded materials directly contradicts the disclosures they made on their own labels. The label for Purdue's OxyContin, for example, acknowledges that its use may increase the risk of serious adverse reactions "including respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, or shock[.]" Likewise, the label for Janssen's Duragesic includes the warning that "[r]espiratory depression is the chief hazard of" Duragesic, and it "has a narrow indication and should be prescribed only by healthcare professionals who are knowledgeable in the administration of potent opioids and management of chronic pain." The labels even include warnings for interactions with substances as commonly used as alcohol, as in the Nucynta ER label, which says that the drug "may be expected to have additive effects when used in conjunction with alcohol . . . [and] respiratory depression, hypotension, and profound sedation, coma or death may result." Yet, upon information and belief, these risks are not highlighted in the educational programs and marketing materials Defendants have sponsored and disseminated; materials that are much more widely read and relied on than the drug labels.

116. The table below (emphasis added) highlights the differences, described above, between how Defendants (in this instance, Janssen) disclosed side effects in unbranded materials and front group materials, versus how they disclosed side effects in their branded advertisements.

Finding Relief: Pain Management for Older Adults (2009)	**Let's Talk Pain Website (2009)**	**Nucynta IR Advertisement (2010)**
[redacted]	[redacted]	branded Janssen advertisement
"At first, the drugs can cause **upset stomach or sleepiness**. These side effects often go away as you get used to the drugs. Some other side effects, such as **constipation**, don't lessen with time. Constipation can be prevented or lessened by taking a laxative on a regular basis."	"The most common side effects of opioids include **constipation, nausea and vomiting, sedation (sleepiness), mental clouding, and itching**. Some people may also experience **dizziness** or difficulty urinating . . . The good news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is	Prescriber information in the ad states: "**Respiratory depression** is the **primary risk** of mu-opioid agonists."

	likely to persist."	

117. In a 2008 warning letter, the FDA recognized that these strategies deceptively represented the side effects of opioids – in that case, Avinza. The FDA complained that one of the company's marketing materials (a file card) lists common adverse effects "including constipation, nausea, and somnolence," but omitted all of the other risks listed in the drug's package insert. According to the FDA, the file card with a page headed "Managing Side Effects"

> creates the misleading impression that the risk information contained in that section is a comprehensive presentation of the risks associated with Avinza therapy and the steps needed to address those risks. The fact that the File Card contains no other disclosure of drug risks reinforces this misleading impression. Furthermore, the File Card – in direct contradiction of the [Package Insert] for Avinza – implies that no serious or life-threatening risks (e.g., risk of respiratory depression, overdose, or death) can be caused by Avinza, both by disclosing only 'common adverse events' (e.g., constipation, nausea, and somnolence) and by emphasizing the drug's 'proven safety and tolerability' throughout the piece. Finally, by framing its discussion of common adverse reactions as one of 'managing' them, and by providing no disclosure to the contrary, the File Card misleadingly implies that common adverse reactions associated with the use of Avinza may ordinarily be alleviated or mitigated, and therefore do not pose a risk to patients.... Your minimization of the serious risk profile associated with your drug raises significant public health concerns.

118. In promoting their opioids, Defendants have engaged in the same marketing practices warned against by the FDA – highlighting only minor risks, emphasizing the ability to manage those risks, failing to disclose serious risks, and generally declaring the safety of their drugs. As the FDA made clear, that message is dangerously deceptive. By deliberately understating the risks of opioids, Defendants exposed patients to extremely dangerous adverse effects and deprived doctors and patients of the ability to make informed, appropriate choices about using opioids.

119. Defendants' pattern of understating the risks of chronic opioid therapies marred the CMEs and studies they funded or sponsored and left providers with the impression that

opioids were much safer than they are and should be used more frequently. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded article on opioids versus another group who reviewed a non-industry-funded article. The industry-funded article did not mention opioid-related death once; the non-industry-funded article mentioned opioid-related death 26 times. A summary of the study notes that students who read the industry-funded article more frequently cited the impression that opioids were underused in chronic non-cancer pain. Those reading the non-industry-funded article, in reporting their "take-aways," mentioned the risk of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty providers have in screening and accounting for source bias.[48]

3. Misrepresentations regarding superiority.

120. Defendants' deliberate misrepresentation of the risks of opioids is particularly evident when compared to Defendants' description of the risk of over-the-counter nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal and renal risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, but also made their omissions regarding the risks of opioids all the more striking and misleading.

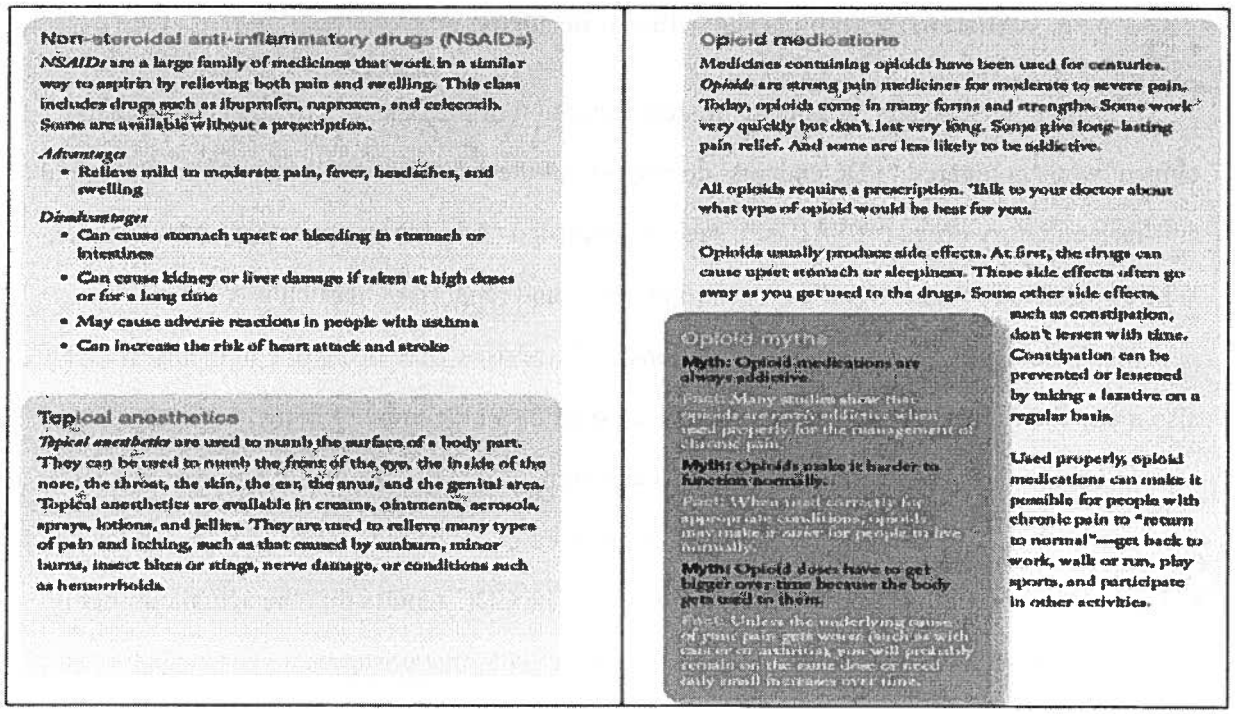
121. In the Cephalon and Purdue-sponsored 2007 APF *Treatment Options*, NSAIDs are described as "life threatening," – a term never used in connection with opioids – and are said to have caused 10,000 to 20,000 deaths each year. The CDC reports that the actual number of deaths even possibly related to the use of NSAIDs in 2008, the most recent year available, is

[48] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), www.pharmedout.org/Fugh-BermanPrescriptionforconflict6-25-10.pdf

roughly 3,400, and that number includes all gastrointestinal bleeding deaths regardless of cause.[49]

122. [redacted]

123. The Janssen-funded brochure, excerpted below, was also distributed to doctors and patients in Chicago during the relevant time period:



Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs are a large family of medicines that work in a similar way to aspirin by relieving both pain and swelling. This class includes drugs such as ibuprofen, naproxen, and celecoxib. Some are available without a prescription.

Advantages

- Relieve mild to moderate pain, fever, headaches, and swelling

Disadvantages

- Can cause stomach upset or bleeding in stomach or intestines
- Can cause kidney or liver damage if taken at high doses or for a long time
- May cause adverse reactions in people with asthma
- Can increase the risk of heart attack and stroke

Topical anesthetics

Topical anesthetics are used to numb the surface of a body part. They can be used to numb the front of the eye, the inside of the nose, the throat, the skin, the ear, the anus, and the genital area. Topical anesthetics are available in creams, ointments, aerosols, sprays, lotions, and jellies. They are used to relieve many types of pain and itching, such as that caused by sunburn, minor burns, insect bites or stings, nerve damage, or conditions such as hemorrhoids.

Opioid medications

Medicines containing opioids have been used for centuries. *Opioids* are strong pain medicines for moderate to severe pain. Today, opioids come in many forms and strengths. Some work very quickly but don't last very long. Some give long-lasting pain relief. And some are less likely to be addictive.

All opioids require a prescription. Talk to your doctor about what type of opioid would be best for you.

Opioids usually produce side effects. At first, the drugs can cause upset stomach or sleepiness. These side effects often go away as you get used to the drugs. Some other side effects, such as constipation, don't lessen with time. Constipation can be prevented or lessened by taking a laxative on a regular basis.

Used properly, opioid medications can make it possible for people with chronic pain to "return to normal"—get back to work, walk or run, play sports, and participate in other activities.

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are rarely addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it easier for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

1 - *Finding Relief: Pain Management for Older Adults*, [redacted] by Janssen (2009)

[49] John Fauber, *NSAID Bleeding Risk: Smoke But No Fire*, MedPage Today (May 30, 2012), www.medpagetoday.com/Geriatrics/PainManagement/32971.

The disclosed risks of NSAIDs include bleeding in the stomach or intestine, kidney or liver damage, and an increased risk of heart attack and stroke. In contrast, the side effects of opioids include an upset stomach, sleepiness, and constipation, though even these side effects often go away or can be managed. [redacted]

124. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.[50]

D. Defendants, Directly and Through Their Agents and Front Organizations, Made and Caused Their Misrepresentations to Be Made and Broadly Disseminated

125. Defendants have polluted virtually every resource for information on the use of opioids to treat chronic non-cancer pain and have created a deceptively solid foundation of core materials, cited and relied upon by others, to minimize the risks and overstate the benefits of using opioids to treat chronic non-cancer pain. Both directly and indirectly – through doctors, medical education courses, seemingly independent patient advocacy groups, and professional societies like AAPM. Defendants have ensured that their messages reach and expand the market for opioids. [redacted] Defendants have identified, encouraged, and compensated high profile KOLs to give talks and advice and author books and articles. Defendants' KOLs offer and serve on the program committees that choose CMEs, and develop and promote treatment guidelines that promote chronic opioid therapy. Many of these groups and KOLs may have been misled by Defendants in the same manner as general practitioners and family doctors.

126. Directly and through public relations firms they hire, and advocacy groups and professional societies they finance and influence, Defendants have funded, drafted, edited,

[50] Mark Olfson et al., *Nat'l Trends in the office-based prescription of schedule II opioids*, 74(9) The Journal of Clinical Psychiatry, 932-939 (Sept. 2013).

approved, published, and distributed websites, books, patient education brochures, videos, and other materials that carry their misrepresentations to targeted groups of doctors (such as family doctors), and patients – particularly veterans and the elderly. Defendants carry out their fraudulent promotions both individually and in concert with other industry front groups and each other, and make and disseminate these misrepresentations throughout the City.

1. Method 1: Key opinion leaders ("KOLs")

127. Defendants routinely rely on a small circle of doctors to promote the use of opioids for the treatment of chronic non-cancer pain. These doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research in order to support the broad use of opioid therapy for chronic non-cancer pain. Known by industry shorthand as "KOLs," or key opinion leaders, they have written, consulted on, edited, and lent their names to books and articles and given speeches and CMEs supportive of chronic opioid therapy. They served on committees that developed treatment guidelines that, even while acknowledging the lack of evidence for their positions, strongly encourage the use of opioids to treat chronic non-cancer pain.

128. [redacted]

129. Defendants' KOLs have served on the boards of the advocacy groups and professional societies that develop and offer CMEs and publish patient education materials on opioids.

130. What Defendants and the KOLs rarely disclose is the substantial sums of money Defendants have paid to the KOLs for consulting and speaking arrangements and to serve on various panels and boards; as well as through purported "research grants." Some KOLs have even gone on to become direct employees and executives of Defendants. Dr. Haddox, for example, was a KOL who, as a physician in private practice, promoted widespread opioid use for chronic non-cancer pain. He was a paid speaker and consultant for Purdue, then became a Purdue senior manager.

131. While some KOLs may initially have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected and funded doctors whose public positions were unequivocal and supportive of using opioids to treat chronic non-cancer pain.[51] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

132. The KOLs' association with Defendants provided not only money, but also prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community. Upon information and belief, using these KOLs is a central part of Defendants' marketing plans and critical to persuading regulators and doctors – who rely heavily and more uncritically on their peers – that the benefits of chronic opioid therapy outweigh its risks. [redacted]

[51] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used key opinion leaders in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.[52] Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN Health (Dec. 20, 2013), http://www.cnn.com/2013/12/20/health/pain-pillar/.

133. Dr. Russell Portenoy, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and co-opted to further their marketing campaign. With Defendants' support, Dr. Portenoy was dubbed the "King of Pain" by TIME MAGAZINE. He co-authored *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases (1986)*, which asserted, based solely on 38 cases, that chronic opioid therapy was a safe and effective treatment for patients with intractable non-malignant pain.

134. Dr. Portenoy, thus, helped to open the door for the use of opioids to treat chronic non-cancer pain. He served on the American Pain Society/American Academy of Pain Medicine Guidelines Committee, which endorsed the use of opioids to treat chronic non-cancer pain, and the FDA Anesthetic and Life Support Drugs Advisory Committee, one of a host of FDA advisory committees that serve to provide expertise and technical assistance to assist the FDA decision-making. While he held these positions, he also was receiving research support, consulting fees, or honoraria from Defendants Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

135. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research. He is a Senior Editor of the *Pain Medicine* Journal, which published numerous articles supportive of chronic opioid therapy. He was President, and is a current board member, of AAPM, a Chicago-based front group that ardently supported chronic opioid therapy. Dr. Webster is the author of numerous CME programs, sponsored by Defendants, which contained virtually all of Defendants' misrepresentations described above. At the same time, Dr. Webster was receiving significant funding (including nearly $2 million from Cephalon).

136. Dr. Webster has been under investigation by the U.S. Drug Enforcement Administration, which raided Dr. Webster's clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic died of opioid overdoses. Ironically, Dr. Webster created

and promoted the Opioid Risk Tool, a screening tool that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids.[52]

137. In a blow to Defendants' marketing campaign, Drs. Portenoy and Webster recently acknowledged shortcomings in their pro-opioid positions. Dr. Webster has admitted that the concept of pseudoaddiction – taking patients at their word and assuming they are not addicts, but just need more pain relief "–became too much of an excuse to give patients more medication . . . It is already something we are debunking as a concept."[53] Dr. Portenoy has admitted that he gave "innumerable lectures in the late 1980s and '90s" in which he asserted that fewer than 1% of patients would become addicted to opioids that "weren't true." Because the primary goal was to "destigmatize" opioids, he said, "we often left evidence behind." Dr. Portenoy also conceded that "data about the effectiveness of opioids does not exist."[54]

2. Method 2: Co-opting of chronic pain advocacy and research groups to promote opioid use.

138. A key component of Defendants' plans to promote the long-term use of opioids was co-opting pain management organizations and societies and pain patient advocacy groups. Taking a page from the tobacco industry, which had created and used front groups to proclaim tobacco was not harmful, Defendants harnessed and warped existing organizations to disseminate their deceptive messages with the expectation that these messages would circulate among and influence the conduct of prescribing physicians and other members of the medical community. These front organizations appeared to be legitimate scientific and patient advocacy

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[52] Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN Health (Dec. 20, 2013), http://www.cnn.com/2013/12/20/health/pain-pillar/.

[53] Ed Silverman, *Opioids & An Overdue Senate Probe: Kolodny Explains*, Pharmalot.com (May 14, 2012), http://www.pharmalot.com/2012/05/opioids-an-overdue-senate-probe-kolodny-explains/.

[54] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), http://online.wsj.com/news/articles/SB10001424127887324478304578173342657044604

organizations (and perhaps started out as such) and publicized seemingly scientific, balanced, and accurate information on opioid use. In fact, the information was false and misleading and paid for and encouraged by Defendants for the purpose of creating a vast market for the use of opioids for chronic non-cancer pain.

139. The role of these organizations in promoting opioid use and their ties to opioid makers was highlighted when, on May 8, 2012, Senators Grassley and Baucus wrote to a half-dozen of these organizations:

> There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic [of opioid use and abuse] by promoting misleading information about the drugs' safety and effectiveness. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Academy of Pain Medicine, the Federation of State Medical Boards, the University of Wisconsin Pain and Policy Study Group, and the Joint Commission.
>
> In a *ProPublica* story published in the *Washington Post*, the watchdog organization examined the American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry."[55] *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers play down the risks associated with opioids and exaggerate their benefits. Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research.
>
> According to the *Milwaukee Journal Sentinel/MedPage Today*, a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers … helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient litigators, position statements, books and doctor education courses."[56]

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[55] Charles Ornstein & Tracy Webber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), http://www.propublica.org/article/the-champion-of-painkillers.

[56] John Fauber, Follow *the Money: Pain, Policy, and Profit*, Milwaukee Journal Sentinel/MedPage Today (Feb. 19, 2012), http://www.medpagetoday.com/Neurology/PainManagement/31256.

140. These front groups, aided by millions of dollars in grants from Defendants and assistance from public relations firms hired by Defendants, spread the misrepresentations central to Defendants' fraudulent promotion of opioids. Indeed, Defendants influenced, if not outright controlled, the messages disseminated by many of these front groups.

a. American Pain Foundation.

141. The most prominent of Defendants' front groups was the American Pain Foundation ("APF"), which received [redacted] in funding from Defendants from 2007 until it closed its doors in May 2012. [redacted]

142. APF issued education guides for patients, reporters, and policymakers that promoted the benefits of opioids for chronic non-cancer pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, described in greater detail below; promotion of opioids to treat veterans has contributed to high rates of addiction among returning soldiers. APF engaged in a significant multimedia campaign – through radio, television and the web – to educate patients about their "right" to pain treatment – namely opioids. KOLs funded by Defendants, including Drs. Perry Fine, Scott Fishman and Kathleen Foley, also served on APF's Board of Directors.

143. In 2009 and 2010, [redacted] of APF's operating budget came from industry sources. Including industry grants for specific projects, in 2009, APF received [redacted] from industry sources out of total income of [redacted]; its budget for 2010 projected receipts of [redacted] from drug companies, out of total income of [redacted]. [redacted]

144. But the control was even more direct than the money. [redacted]

[redacted]

145. [redacted] opioid "tool-kit" for the National Initiative on Pain Control [redacted] included two of Defendants' key misrepresentations:

- After starting opioid therapy, you may see the following positive improvements: - Your pain level may decrease[;] -Your level of function should improve: you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse[;] - Your sleep may improve.
- People who take opioids as prescribed usually do not become addicted.

146. At a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the oxycontin criminal settlement," APF aggressively defended Purdue, repeatedly denying that patients prescribed opioids abuse or become addicted to the drugs. APF's board chairman, Dr. James Campbell, described addiction as a "rare problem" for chronic non-cancer pain patients and asserted that "the scientific evidence suggests that addiction to opioids by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of oxycontin and the abuse and diversion of the drug."

147. Despite APF's unequivocal pro-opioid positions, [redacted]

[redacted]

148. On May 8, 2012, Senators Grassley and Baucus wrote the Chairman of APF seeking information about the source of its funding and asked for a response by June 8, 2012. APF shuttered its offices and dissolved before that deadline.

b. American Academy of Pain Medicine.

149. The American Academy of Pain Medicine with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs critical to Defendants' deceptive marketing of chronic opioid therapy. [redacted] AAPM created and maintained a corporate relations council, whose members paid $25,000 a year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with the AAPM's marquee event – its annual meeting in Palm Springs. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

150. Additionally, AAPM retained pro-opioid KOLs to serve on its board of directors, and advisory committees; further, allowing the organization to be used to promulgate the pro-opioid misrepresentations being pushed by the opioid manufacturers. Notably, one of AAPM's recent past presidents, Dr. Lynn Webster, was appointed to the position while he was being

[redacted]

investigated by the DEA as a result of more than 20 deaths of chronic pain patients of Dr. Webster's clinic, who were prescribed and were taking prescription opioids. Another outspoken pro-opioid KOL, Dr. Russell Portenoy, also served as a recent past president of AAPM.

151. The AAPM and the American Pain Society issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Defendant Purdue; three years later, he became Vice President for Health Policy at Purdue. AAPM and the American Pain Society issued guidelines in 2009 and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the guidelines, including KOL Dr. Portenoy, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Upon information and belief, the 1997 consensus statement remained on AAPM's website until 2011, and was taken down only after a doctor complained.

3. Method 3: Treatment guidelines.

152. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts in, nor trained in, the treatment of chronic non-cancer pain. Treatment guidelines used in making treatment decisions are cited throughout the scientific literature and are referenced by third-party payers in determining whether they should cover treatments for specific indications.

153. As noted above, in 2009 AAPM, together with the American Pain Society ("APS"), issued their *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain*. The Guidelines represented a marked departure from previous guidelines for the promotion of opioids. The APS/AAPM guidelines promote opioids as "safe and effective" for treating chronic non-cancer pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients with and without past abuse histories. One

member of the panel, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and the founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions by Defendants to the sponsoring organizations and committee members. These guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but the body of scientific evidence on opioids; the APS/AAPM guidelines have been cited 732 times in academic literature that was disseminated in Chicago during the relevant time period, are still available on the internet, and were reprinted in the *Journal of Pain*.

154. In 2009, the American Geriatric Society ("AGS") revised its guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. [redacted] included the following recommendations:

- "All patients with moderate to severe pain … should be considered for opioid therapy (low quality of evidence, strong recommendation)."
- "[Th]e risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."

These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence.

155. According to one news report, AGS received $344,000 in funding from opioid makers since 2009.[58] Five of 10 of the experts on the guidelines panel disclosed financial ties to

[58] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee Journal Sentinel/MedPage Today (May 30, 2012), http://www.medpagetoday.com/Geriatrics/PainManagement/32967.

Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock.[59]

156. In contrast, treatment guidelines that did not receive industry backing are much more reserved and endorse chronic opioid therapy only in narrow circumstances. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians, included a disclaimer that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." The American Society of Interventional Pain Physicians Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." They recommend long-acting opioids in high doses only "in specific circumstances with severe intractable pain … with continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."

157. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommended against "routine use of opioids for treatment of chronic pain patients," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.

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[59] The Institute of Medicine recommends that, to ensure an unbiased result, that fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

158. Industry supported guidelines, in contrast, separate the strength of the recommendation from the strength of evidence supporting the recommendation. For instance, most of the "strong" recommendations of the APS/AAPM guidelines are backed by only what the guidelines describes as weak evidence. Further, the guidelines Defendants supported fail to adequately take into account the potential adverse effects and specific label warnings that a physician should take into consideration in deciding on a treatment for any medical condition. As a result, they present a distorted picture of treatment options.

159. The separation of recommendations from the strength of supporting evidence proved useful for drug companies in promoting their opioids individually. [redacted] Upon information and belief, the guidelines were widely referenced and promoted by the drug companies and their KOLs and front groups without disclosing the acknowledged lack of evidence to support them. This dangerously misrepresented to doctors the credibility and applicability of the pro-opioid recommendations.

4. Method 4: Continuing medical education.

160. The millions of doctors and other health care professionals[60] who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. Defendants have sponsored thousands of CME programs that promote chronic opioid therapy and support and disseminate the deceptive and biased messages described in this Complaint. Upon information and belief, Defendants' grant making to fund and sponsor CMEs has been

[60] Lisa M. Schwartz & Steven Woloshin, *Medical Communication Companies and Continuing Medical Education: Clouding the Sunshine*, 310(23) The Journal of the Am. Med. Ass'n 2507, 2507 (Dec. 18, 2013).

influenced by their marketing strategies and harnessed to the goal of increasing opioid sales. Upon information and belief, Defendants are more than passive funders of these programs, which reached tens of thousands of doctors; they have influenced, if not outright controlled, the messages on topics and in the fields of practice Defendants targeted.

161. The American Medical Association has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[61]

162. Defendants have long-standing relationships with the professional associations, advocacy organizations, presenters, and CME development companies that select and develop opioid-related CMEs. These other organizations have depended upon Defendants' financial support for their activities and, in some cases, their very existence. It stands to reason that each of these organizations and the individuals running them know and believe that future financial support from Defendants depends upon producing programs that support the use of Defendants' products.

163. Defendants are able to influence CMEs because they fund: (1) the KOLs who serve on the program committees of the professional societies that select the presentations and speakers and promote the views on which the presentations rely; (2) the KOLs who serve as speakers for the CMEs; and (3) the professional societies that host the conferences at which the presentations are given. Upon information and belief, many of these programs focus exclusively on prescribing opioids, and do not fairly present reasonable alternative treatments (except to discount them), nor do they fairly present (or present at all) the risks or benefits of chronic opioid therapy, nor how to take patients off opioids, once prescribed.

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[61] *Opinion 9.0115 – Financial Relationships with Indus. in CME*, Am. Med. Ass'n (Nov. 2011), http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion90115.page.

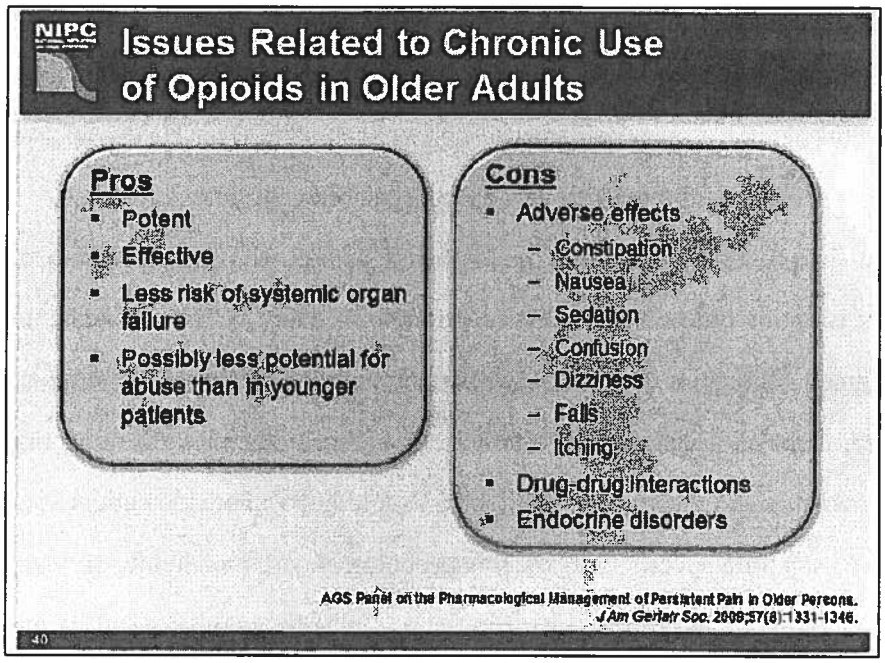
164. Defendants' sales representatives participated in conferences at which the CMEs were presented, encouraged doctors to attend the programs, and held auxiliary events that reinforced and amplified the distorted messaging of the CMEs. The CMEs themselves, however, buttressed by printed disclaimers by Defendants, were marketed to appear evidence-based and unbiased. In fact, like KOLs, the CMEs are particularly effective for disseminating Defendants' messages because doctors rely on these peer-led professional events to deepen their understanding of clinical issues.

165. *Path of the Patient, Managing Chronic Pain in Younger Adult at Risk for Abuse*, a CME program sponsored in part by Purdue and edited by KOL Dr. Perry Fine, provides one example of Defendants' use of CMEs to spread deceptive messages supportive of chronic opioid therapy. *Path of the Patient* aimed to educate primary care doctors about managing chronic non-cancer pain with opioids. The presentation is devoted entirely to opioid prescribing and, despite its title, presents *no other* potential treatments. Far from a therapy of last resort, as conventional medical thought advised, *Path of the Patient* promotes opioid therapy as the only solution, even for common chronic non-cancer pain issues such as back pain. This CME was available on-line for Chicago physicians, and others, to view during the relevant time period.

166. In a role play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills a day as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Even given these facts, an authoritative narrator notes that, because of a condition known as pseudoaddiction, the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long-acting opioid.

167. An Endo-sponsored CME put on by the APF's National Initiative for Pain Control, *Persistent Pain in the Older Adult*, similarly reprises several of Defendants' misrepresentations. The program was first made available on-line, including to Chicago

physicians, and others, in 2011 and continued to be available during the relevant time period. The CME describes fear of addiction, safe use, and drug-drug interactions – all factors relating to addiction, abuse, and overdose – as the most significant barriers to treating "persistent" or chronic non-cancer pain in the elderly. The presentation counsels that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). Citing the AGS's treatment guidelines as its sole support, the CME describes the "chronic use of opioids in older adults" as "effective" and notes "possibly less potential for abuse than in younger patients." Its listed adverse outcomes simply omit addiction, overdose, respiratory depression, or death, among others, and the slides note that tolerance to opioids more mild side effects (such as dizziness or nausea) "develops within days to weeks." The CME never discloses the heightened risks opioids pose to elderly patients (see below).



168. Dozens of CMEs that were available during the relevant time period and continue to be available to doctors in Chicago during the relevant time period also promoted the false concepts that opioids improve quality of life and physical function, that the risk of addiction to

opioids is low and that doctors can identify and manage patients at higher risk of addiction. The programs train doctors to use specific risk training tools without disclosing that the tools are unproven or the lack of evidence that high-risk – or any – patients can take opioids long-term without becoming addicted.

5. Method 5: Scientific articles.

169. Defendants rely on misleading and deceptive citation of scientific articles to overstate the benefits of chronic opioid therapy and minimize its serious risks and fail to disclose contrary evidence. For instance, the Purdue-funded *Policymaker's Guide* (2011) makes the particularly callous representation that less than 1% of children prescribed opioids will become addicted. In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain. The purpose of the *Guide* was to support opioid therapy generally; it was not focused on or restricted to cancer pain patients — the only population addressed in Dr. Foley's article, which also did not reference pediatric cancer patients or include any statistics on addiction rates. Purdue funded and distributed the Guide with this misleading citation, knowing that there was no evidence to support the general assertion that children will not become addicted to opioids, even when taken long-term. The Guide was disseminated in Chicago within the relevant time period.

170. Similarly, a 2003 scientific study funded by Purdue and co-authored by a Purdue employee concluded that OxyContin is "effective and safe for the management of [chronic diabetes-related pain] and improves QOL [quality of life]." The study asserts that there is "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse." The authors cite a single article by Porter and Jick, *Addiction Rare in Patients Treated with Narcotics*, published in the prestigious NEW ENGLAND JOURNAL OF MEDICINE. What the authors fail to disclose is that the "evidence" is actually a letter to the editor, not a peer reviewed article. Moreover, the letter describes not a study but a chart review of hospitalized patients; if medical charts failed to note that the patients exhibited documented

signs of addiction while on opioids, the authors concluded that they were not addicted. Not only did the study not support the authors' assertion, but the authors' misleading citation of it created a false impression of its reliability. The Porter and Jick letter and the 2003 Purdue study have been cited 819 and 455 times, respectively, in the medical literature since 2008.

171. Practicing doctors, particularly the busy family doctors and general practitioners targeted by Defendants, do not have the time to look behind seemingly authoritative sources, particularly in scientific literature. They do – and must be able to – rely on citations to scientific literature, a fact that Defendants use to their advantage. Moreover, the misleading use of studies to give them weight or meaning they do not have is like a virus; once embedded in the literature, it takes on a life of its own. Studies that assert addiction is rare, relying either on the Foley or Porter-Jick analyses, themselves are cited for the proposition. Thus, with a few key manipulations and deceptive citations, Defendants were able to seed a scientific consensus supportive of chronic opioid therapy.

6. Method 6: Patient education.

172. Defendants reach chronic non-cancer pain patients through written publications, websites, and videos designed to present the purported "facts" about opioids in a simple, user-friendly manner. As Defendants know, these materials are accessed by both patients doing their own research and doctors, who read them when distributing them to patients. The materials Defendants produced concerning opioids include numerous fraudulent representations, overstate the benefits of chronic opioid therapy, and fail to fully disclose its risks, particularly the risks of addiction.

173. [redacted] The pamphlet, *Finding Relief: Pain Management for Older Adults* (2009, also sponsored by AGS, and American Academy of Pain Medicine) is unbranded, [redacted]

174. *Finding Relief* describes opioids as "rarely addicting when used properly for the management of chronic pain" and assures that "unless the underlying cause of your pain gets worse … you will probably remain on the same dose or only need small increases over time." As described above, these contentions are wholly lacking in scientific or clinical support.

[redacted]

175. Defendants created campaigns – including literature, websites, community groups, and programs – related to chronic non-cancer pain from illnesses such as lower back pain, shingles, migraines, osteoarthritis, phantom limb pain, fibromyalgia, and multiple sclerosis. These conditions affect significant numbers of people, who have formed affinity groups and on-line communities for support in seeking to address conditions that produce persistent pain and may necessitate long-term treatment. Defendants used this community-building to promote the use of opioids in the treatment of these conditions, despite the fact that there was little or no scientific evidence supporting the use of opioids for these conditions, and little or no evidence supporting or even suggesting that the use of opioids for these conditions would provide more benefit from pain relief than harm from the many known and significant opioid treatment risks. None of these conditions reflect indications approved to appear on Defendants' drug labels, supporting the inference that Defendants did not have evidence to obtain such approval.

176. In addition to their general marketing efforts, Defendants made special efforts to market to two particularly vulnerable patient groups: the elderly and veterans. While obvious markets for chronic non-cancer pain medications, each of these patient populations has risk factors that make long-term opioid use particularly dangerous.

a. Elderly patients

177. Elderly patients taking opioids have been found to suffer elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels,

occurs more frequently in elderly patients.[62] A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[63] Defendants' targeted marketing to the elderly and the absence of cautionary language in its promotional materials flies in the face of scientific evidence and even their own labels and creates a heightened risk of serious injury.

178. In their effort to reach elderly patients, who experience pain associated with arthritis and other aging-related conditions, [redacted] education materials focused on elderly patients. *Finding Relief: Pain Management for Older Adults*, a 2009 publication sponsored by Janssen, as noted above, repeated the same unsubstantiated, deceptive statements that opioids are "rarely addictive" and increase patients' function, allowing them to get back to work or participate in recreational activities.

179. Upon information and belief, other Defendants also focused outreach efforts on the elderly. [redacted]

180. Defendants also promoted the notion – also without adequate scientific foundation – that the elderly are particularly unlikely to become addicted to opioids. The AGS's 2009 Guidelines, for example, described addiction rates as "exceedingly low in older patients with no current or past history of substance abuse." Yet, a 2010 study that examined overdoses among long-term opioid users found that the largest number of patients among those with serious overdoses were 65 or older.[64]

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[62] Kathleen W. Saunders et al., *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, 25(4) Journal of Gen. Internal Med., 310-315 (Apr. 2010).

[63] Daniel H. Solomon et al., *The Comparative Safety of Analgesics in Older Adults with Arthritis*, 170(22) Archives of Internal Med., 1968-1976 (Dec. 13, 2010).

[64] Kate M. Dunn et al., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Annals of Internal Med. 85, 89 (Jan. 19, 2010).

181. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

b. Veterans

182. Veterans, too, are suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed prescription drug abuse among military personnel doubled from 2002 to 2005 and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they did in 2001.[65] Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days.[66] Although, upon information and belief, many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving Veterans' Administration ("VA") services nationally in a single year (2005), 1,013 had died of accidental drug overdoses – double the rate of the civilian population. VA facilities outside of Chicago, which, upon information and belief, serve Chicago residents who are veterans, saw dramatic increases in their rates of prescribing opioids.

183. Opioids are particularly dangerous to veterans. According to a study published last year in the Journal of American Medicine, veterans returning from Iraq and Afghanistan prescribed opioids have higher incidence of adverse clinical outcomes, like overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause

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[65] Bill Briggs, *VA Docs Defied Opiate Rules in Treating Vets, Audit Finds*, NBC News (May 15, 2014), http://www.nbcnews.com/storyline/va-hospital-scandal/va-docs-defied-opiate-rules-treating-vets-audit-finds-n106461.

[66] American-Statesman Investigative Team, *Prescription drug abuse, overdoses haunt veterans seeking relief from physical, mental pain*, Austin American-Statesman (Sept. 29, 2012), http://www.statesman.com/news/news/prescription-drug-abuse-overdoses-haunt-veterans/nSPLW/

respiratory depression and death.[67] Yet, according to a Veterans Affairs Office of Inspector General Report, 92.6% of veterans chronically prescribed opioid drugs were also prescribed benzodiazepines.[68] Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and failed to disclose in their promotional materials the known, serious risks opioids posed to them.

184. Defendants have targeted veterans with fraudulent and unproven representations. As early as 2001, a Purdue promotional plan described spending hundreds of thousands of dollars to target the Veterans Administration and admitted that it was using "education" for what was actually marketing.[69] "Corporate initiatives and partnering efforts were very successful with the Veterans Administration. In addition to building sales for OxyContin tablets, it also positioned Purdue as the leader in pain management education."[70]

185. *Exit Wounds*, a 2009 publication [redacted] promoted as a personal narrative by one veteran writing to others, describes opioids as "under-used" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "*increase* your level of functioning" (emphasis in original) and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The book also asserts that "denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of

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[67] Karen H. Seal et al., *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan*, 307(9) The Journal of the Am. Med. Ass'n, 940-947 (Mar. 7, 2012).

[68] Briggs, *supra* note 65.

[69] American-Statesman Investigative Team, *Critics say pharmaceutical firms spurred the increase in prescriptions for narcotic painkillers,* Austin American-Statesman (Sept. 29, 2012), http://www.statesman.com/news/news/local-military/critics-say-firms-spurred-painkiller-prescriptions/nSPNL/

[70] *Id.*

State Medical Boards." The U.S. Federation of State Medical Boards itself received support from Defendants during the time it created and published its guidelines for prescription of opioids. Upon information and belief, *Exit Wounds* was disseminated in Chicago within the relevant time period.

186. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with anti-anxiety medications taken by a significant number of veterans. [redacted]

187. The deceptive nature of *Exit Wounds* is made obvious in comparing it to guidance on opioids published by the VA and Department of Defense ("DOD") in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses or using multiple doctors for prescriptions and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death – none of which are disclosed in *Exit Wounds*. *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the DOD, discloses that its review "revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps … include: lack of effectiveness studies on long-term benefits and harms of opioids …; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification …; lack of evidence on the utility of informed consent and opioid management plans …; and treatment of patients with chronic noncancer pain at higher risk for drug abuse or misuse." These disclosures are missing from Defendants' marketing to veterans.

E. Defendants Often Acted Together in Promoting Opioids, Opposing Regulation and Facilitating Supportive Standards to Approve Opioids

188. As laid out above, Defendants supported, assisted, encouraged and/or facilitated the same front groups and KOLs to disseminate the same deceptive messages about the use of opioids to treat chronic non-cancer pain. In fact, the similarity of their messages, language, and even their formatting (*e.g.*, the myth/fact formulation) suggests that Defendants participated in a common scheme to disseminate misleading information about opioids.

189. This inference is supported by Defendants' cooperation in other activities to promote opioids, including successful efforts to set standards for measuring and treating pain, training and regulating doctors, and approving new opioids.

190. Defendants' efforts to shift the paradigm on opioids and pain treatment began soon after their branded opioids were launched. In 2000, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), in conjunction with the University of Wisconsin Pain and Studies Group, declared that pain was the "5th Vital Sign" and required all healthcare practitioners to make pain assessment and management a priority in daily practice.

191. Upon information and belief, the impetus behind the new pain standard began with June Dahl, then a professor of pharmacology at the University of Wisconsin-Madison. Dr. Dahl approached JCAHO with a proposal and helped identify pain management experts and key organizations to act as advisors to JCAHO, as well as promoters of Pain as the 5th Vital Sign. Those experts and key organizations are many of the same heavily funded KOLs and front groups that ultimately helped bring about the change in attitudes towards opioids and, subsequently, the rise in opioid prescribing. Defendant Purdue was one of two companies that paid for programs across the country to educate hospital physicians and staff about complying with the new pain standards and had exclusive rights to distribute certain education materials to JCAHO members.[71]

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[71] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem,* U.S. Gen. Accounting Office (Jan. 22, 2004), www.gao.gov/htext/d04110.html.

192. Once health practitioners were required to consider a patient's pain along with other vitals, the next step was to convince practitioners that all pain must be treated – preferably with opioids. In 2004, the Federation of State Medical Boards revised and updated its Model Policy for the Use of Controlled Substances for the Treatment of Pain. In support of those efforts, noted KOL Dr. Scott Fishman was tapped to author a companion piece, titled *Responsible Opioid Prescribing: A Physician's Guide* (2007)

193. The Guide was sponsored by Defendants Endo, and Purdue and was distributed to state medical boards, healthcare regulatory boards, medical organizations, hospitals and physicians across the country, including in Chicago. [redacted] The *Physician's Guide* contained many of the misrepresentations described above, notably the concept of pseudoaddiction and the claim that opioids improve function. [redacted]

194. Defendants also worked together to promote opioids through the Pain Care Forum. The Forum is comprised of representatives from opioid manufacturers and distributors (including each of the Defendants); doctors and nurses in the field of pain care; health care professional organizations (*e.g.*, American Academy of Pain Management, American Pain Society, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and the American Chronic Pain Association); and other like-minded organizations (*e.g.*, Federation of State Medical Boards and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants. Upon information and belief, the Pain Care Forum was started, and continues to be run, by Defendant Purdue's in-house lobbyist Burt Rosen, previously in conjunction with APF. [redacted]

195. Upon information and belief, Defendants collaborated on a common campaign to build a market for opioids for chronic non-cancer pain, which they could share. .

F. Defendants Also Acted Individually to Deceptively Promote Their Opioids for Chronic Non-Cancer Pain.

196. In addition to participating in a shared campaign to expand the market for opioids by reaching chronic non-cancer pain patients and conditions, each Defendant acted on its own to deceptively market its specific opioids for chronic non-cancer pain and to capture a larger share of the chronic non-cancer pain market. Separately, in their branded materials and on seemingly independent websites, they each overstated the benefits and understated the risks of their drugs in the various ways described above, often causing the FDA to formally admonish them. On top of this, Cephalon engaged in additional unlawful conduct, marketing its opioid Fentora for unapproved chronic pain uses despite only recently settling a case involving almost identical activities with respect to its predecessor, Actiq. A review of the City's claims also suggests that opioids were prescribed, and potentially marketed, for off-label uses to treat depression. Purdue also quickly began to violate a consent judgment with the federal government and the State of Illinois by continuing to misrepresent the risks and benefits of OxyContin and its other opioids.

1. Cephalon fraudulently marketed Actiq and Fentora.

197. Cephalon also engaged in a distinctive effort to market its opioids for chronic non-cancer pain despite having labels that specifically limited their use to cancer pain. As a result of its successful marketing efforts, Cephalon reaps significant revenue from selling its opioids for treatment of chronic non-cancer pain. However, neither of its two opioid drugs – Actiq or Fentora – is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction and in order to claim its piece of the broader chronic non-cancer pain market, Cephalon deceptively and unlawfully marketed Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed, causing prescriptions to be written and paid and, grievously, patients to be injured and die.

a. Cephalon launches its fraudulent marketing scheme of Actiq.

198. Cephalon's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate." [72]

199. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain. Actiq is a rapid onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose for patients who are not opioid tolerant, that is, patients who have taken specific dosages of opioids for a week or longer and whose systems have acclimated to the drugs.

200. In 1995, the FDA approved Actiq "**ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." (Emphasis in FDA document.) Because of Actiq's dangers, wider, off-label uses – as the FDA label makes clear – are not permitted:

> Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients."
>
> Actiq is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

[72] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs,* The Wall Street Journal (Nov. 3, 2006), http://online.wsj.com/news/articles/SB116252463810112292.

(Emphasis in original.) Unlike other drugs, where off-label uses are permitted but cannot be promoted by the drug maker, Actiq is so potent that off-label use to opioid naïve patients is strictly forbidden.

201. Notwithstanding the drug's extreme potency and related dangers and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic non-cancer pain – an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports related injuries, and other conditions not associated with cancer for which it was not approved, appropriate, or safe.

202. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population. But by 2005, Actiq sales reached $412 million, making it Cephalon's second highest selling drug. As a result of Cephalon's deceptive, unlawful marketing, sales exceeded $500 million by 2006.

b. Cephalon fraudulently marketed Actiq's successor drug, Fentora.

203. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, Cephalon purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application (NDA) to the FDA for approval.

204. Like Actiq, Fentora is an extremely powerful opioid. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth. Like Actiq, Fentora is a rapid onset opioid.

205. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already receiving and were tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

206. Fentora's inherent danger is confirmed by the unusually strong and detailed black box warning label – the most serious medication warning required by the FDA. The warning makes clear that, among other things:

> Reports of serious adverse events, including deaths in patients treated with *FENTORA* have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of *FENTORA* for any other fentanyl product may result in fatal overdosing.
>
> *FENTORA* is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
>
> FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients,"
>
> . . .
>
> *FENTORA* is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

(Emphasis in original.)

c. October 1, 2006 – Cephalon launches Fentora and immediately begins deceptive marketing campaign.

207. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it developed for Actiq and simply substituted in Fentora. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably be off-label.

208. Cephalon's marketing of Actiq "primed the market" for Fentora. Cephalon had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally – not breakthrough cancer pain in particular – from Actiq.

209. On February 12, 2007, only five months after the launch, Cephalon CEO Frank Baldino told investors:

> [W]e've been extremely pleased to retain a substantial portion, roughly 75% of the rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.[73]

210. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses. He identified two "major opportunities" – treating breakthrough cancer pain and:

> The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain. . . . .
>
> We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . Noting that opioids are "widely used in the treatment of . . . non-cancer patients," Roche continued:
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[74]

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[73] *See Cephalon Q1 2007 Earnings Call Transcript,* Seeking Alpha (May 1, 2007, 8:48 PM EST), http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript (last visited May 27, 2014).

[74] *Id.*

d. September 2007 – Reports of death and serious side effects lead the FDA to issue a public health warning for Fentora.

211. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora and indicating that "[t]hese deaths occurred as a result of improper patient selection *(e.g.*, use in opioid non-tolerant patients), improper dosing, and/or improper product substitution." The warning did not acknowledge Cephalon's deliberate role in the "improper patient selection."

212. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora only should be prescribed for approved conditions and that dosage guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label use. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, post-operative pain, or pain due to injury, and that it should be given only to patients who have developed opioid tolerance. The Advisory reiterated that because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.

e. Cephalon sponsored CMEs used to promote the off-label use of Actiq and Fentora – 2007-2008, in spite of the FDA warnings.

213. Cephalon also used the CME programs it sponsored to promote the off-label use of their Actiq and Fentora. In 2007 and 2008, Cephalon sponsored three CMEs available to Chicago physicians that each positioned Actiq and Fentora, and only Actiq and Fentora, as "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs only use the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME would know to prescribe Actiq or Fentora.

214. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and

Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Lynn R. Webster and M. Beth Dove. It recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid onset opioid when it cannot. The only examples of rapid onset opioids then on the market are oral transmucosal fentanyl citrate (*i.e.*, Actiq) or fentanyl effervescent buccal tablet (*i.e.*, Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients *and are frequently prescribed to treat [breakthrough pain] in noncancer patients as well*." (Emphasis added.)

215. Similarly, *Breakthrough Pain: Improving Recognition and Management*, offered between March 31, 2008, and March 31, 2009, by Medscape, LLC completely omitted tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like the "Optimizing Opioid Treatment" CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, *Opioid-Based Management of Persistent and Breakthrough Pain*, with Dr. Christine A. Miaskowski. They instruct their audience, "Clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommend "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," *i.e.*, Actiq, and "fentanyl buccal tablet," *i.e.*, Fentora, including specifically in patients with chronic non-cancer pain.

216. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines that she served on Cephalon's speakers' bureau. Dr. Fine and Dr. Webster also received funding from Cephalon for consulting services, and upon information and belief, Drs. Fine and Webster continued to receive funding from other opioid manufacturers, too.

f. May 6, 2008 – The FDA rejects Cephalon's request for expanded approval of Fentora.

217. Cephalon filed a supplemental new drug application, ("sNDA"), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. To support its application, Cephalon admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.[75] Cephalon argued for the expanded approval even though, as it acknowledged, "[t]o date, no medication has been systematically evaluated in clinical studies or approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain." *Id.*

218. The FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.[76] By a vote of 17-3, the relevant Advisory Committee – a panel of outside experts – voted against recommending approval of Cephalon's sNDA for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied Cephalon's application and requested, in light of its already off-label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk Management Program. In December 2008, the FDA followed that up with a supplemental request, asking that the company submit a Risk Evaluation and Mitigation Strategy for Fentora as well.

g. March 26, 2009 – the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned Cephalon about its misleading advertising of Fentora.

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[75] *See Fentora (fentanyl buccal tablet) CII: Advisory Comm. Briefing Document,* U.S. F.D.A. Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (Apr. 4, 2008), http://wwvv.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf (last visited May 27, 2014).

[76] *See Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System ("AERS") Database*, U.S. F.D.A. Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008),, http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDA-corepresentations.ppt#289,1 (last visited May 27, 2014).

219. Undeterred by the rejection of its sNDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade over Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, Cephalon also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not simply those who were opioid tolerant.

220. On March 26, 2009, the DDMAC issued a Warning Letter to Cephalon, telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug. Specifically, the Warning Letter asserted that a direct-to-patient advertisement found on the internet was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora therapy … when this is not the case." DDMAC emphasized that Fentora's label was limited to cancer patients with breakthrough pain **"who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."** (Emphasis in original.) DDMAC explained that the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original.) DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (Emphasis in original.)

h. Cephalon continues to knowingly, deceptively, and illegally promote Fentora for off-label uses.

221. Cephalon's own market research studies confirm that its Fentora promotions were not focused on the physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market

potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

222. Yet Cephalon continued to use its general pain sales force (which numbered over 110 representatives) to promote Fentora to general pain specialists.

223. Cephalon-set sales quotas for its general pain sales force would be unattainable if they did not deceptively promote Fentora off-label. The general pain sales representatives have, from the outset, been required to adhere to call lists that include numerous pain doctors and other physicians who do not, and would not, prescribe Fentora on-label. These same call lists contain few, if any, oncologists.

224. A 2009 PowerPoint presentation by Kathy Roman, Cephalon's Associate Director of Oncology for Strategic Analysis & Planning, reported that only 4% of Fentora prescriptions were written by oncologists. [redacted]

225. Cephalon's conduct in marketing Actiq and Fentora for chronic non-cancer pain, despite their clear (and deadly) risks and unproved benefits, was an extension of, and reaped the benefits of, Cephalon's generally deceptive promotion of opioids for chronic non-cancer pain.

2. Purdue's role in deceptively promoting opioids for treatment of chronic non-cancer pain.

226. Like Cephalon, Purdue also undertook its own separate campaign to deceptively market opioids. Purdue is the maker of OxyContin, which, over time, has been the most used and abused opioid. Today, with one exception, all of the drugs marketed by Purdue are opioids.

a. Purdue's marketing of OxyContin was deceptive from the start.

227. OxyContin was approved by the FDA in 1995 for "management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." Purdue immediately began promoting OxyContin as less addictive than other opioids. The drug's extended-release mechanism, according to Purdue, meant it was less likely to provide a euphoric high and therefore was less likely to be abused, create addiction, or cause withdrawal. However, Purdue "did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications."[77] When crushed, dissolved in water, or injected, OxyContin's extended-release mechanism could be bypassed to produce a heroin-like high. In fact, OxyContin was more likely than other opioids to be abused and diverted because it had more oxycodone than other non-controlled release opioids (and oxycodone already is twice as potent as morphine).

228. Purdue's marketing persuaded primary care physicians that it was safe to prescribe OxyContin for chronic non-cancer pain. By 2003, according to the Government Accountability Office ("GAO"), general practitioners represented half of all OxyContin prescribers.[78] A GAO report noted that, between 1997 and 2002, OxyContin prescriptions for non-cancer pain increased nearly ten-fold, from 670,000 to 6.2 million, versus an increase in

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[78] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem, supra* note 71.

[78] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem, supra* note 71.

prescriptions for treatment of cancer pain from 250,000 to 1 million; non-cancer prescriptions represented 85% of total OxyContin prescriptions. At the same time, Purdue doubled the number of its sales representatives, who received bonuses based on sales quotas and were directed to target the most prolific opioid prescribers. Total sales bonuses in 2001 were $40 million, up from $1 million in 1996. Purdue also used speakers bureaus, which put on programs at resort locations, starter coupons to attract new patients, funded new front group websites, and, even distributed plush toys and hats, which the Drug Enforcement Administration ("DEA") says had never been done before for a controlled substance. The DEA blamed Purdue's "aggressive marketing of OxyContin" for "fuel[ing] demand for the drug and exacerbat[ing] the drug's diversion.[79]

229. In 2001, the FDA required Purdue to narrow its approved indication to "moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time" and added new warnings relating to the drug's potential for misuse and abuse. In August of that year, the FDA wrote to Purdue to make clear that all promotional materials should prominently disclose the new label information. Yet, not 18 months later, in January 2003, in response to two ads Purdue ran in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, the FDA issued a sharply worded warning letter to Purdue:

> Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of risk. In addition, your journal advertisements fail to present in the body of the advertisements critical information regarding limitations on the indicated use of OxyContin, thereby promoting OxyContin for a much broader range of patients with pain than are appropriate for the drug. The combination in these advertisements of suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks

[79] *Id.*

> associated with its use is especially egregious and alarming in its potential impact on the public health.[80]

230. The FDA's strong language seemed to have little impact on Purdue's behavior. In 2007, Purdue entered into a $635 million settlement with the federal government to resolve civil and criminal allegations relating to its marketing of OxyContin. This was a minor cost compared to the $27 billion in sales revenue generated since the introduction of OxyContin in 1996.[81] Purdue pled guilty to a single felony count of misbranding and its chief executive officer, chief medical officer, and general counsel individually pled guilty to misdemeanor counts. Purdue admitted in its plea that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science.

231. As part of its settlement, Purdue entered into a Corporate Integrity Agreement with the United States Department of Health and Human Services-Office of Inspector General ("HHS-OIG"). Purdue agreed to refrain from deceptively marketing OxyContin, to train its employees regarding compliance with the Agreement, monitor its own compliance, and report its compliance (both independently and through an independent review organization or "IRO") to HHS-OIG.

b. Purdue continued to engage in false marketing, misrepresenting OxyContin's benefits and the risk of addiction when taken long-term for chronic non-cancer pain.

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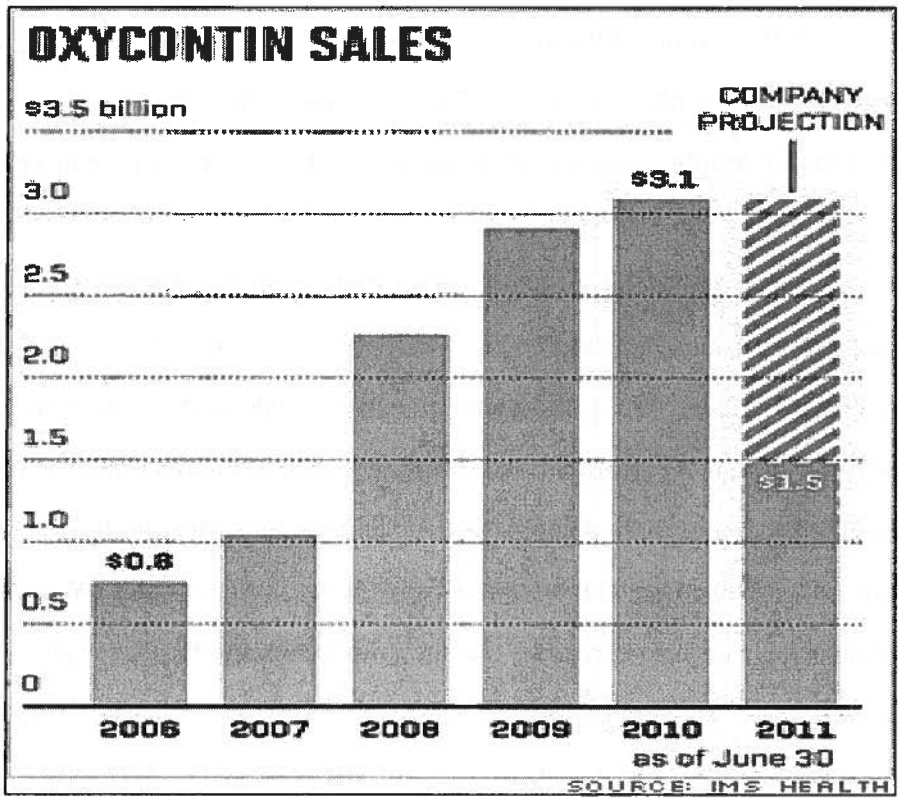
[80] Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Mktg., Adver., and Commc'ns , U.S. F.D.A., to Michael Friedman, Executive Vice President and C.O.O., Purdue Pharma L.P. (Jan. 17, 2003), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM168946.pdf.

[81] Scott Glover & Lisa Girion, *OxyContin Maker Closely Guards Its List of Suspect Doctors,* Los Angeles Times (Aug. 11, 2013), articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811.

232. Despite its guilty plea, Purdue continued to deceptively market opioids. And, as a result, its sales continued to grow. OxyContin yielded $3.1 billion in revenue for Purdue in 2010, up four-fold from its 2006 sales of $800 million.



233. Purdue's direct misrepresentations, and its relationship with front groups and KOLs who advanced its deceptive marketing, are described above. Upon information and belief, Purdue deployed these doctors and front groups according to marketing strategies it developed, and also funded, directed, shaped, approved, and disseminated their misrepresentations regarding the risks, benefits, and superiority of opioids' use to treat chronic non-cancer pain.

c. Purdue was aware of, and has profited from, misuse and diversion of its opioids.

234. According to the GAO, the first public news of diversion and abuse of OxyContin became known in 2000. Among them were reports of patients arriving in emergency rooms with severe withdrawal or overdoses, hundreds of deaths, and increases in drug treatment admissions

for individuals on OxyContin. Since 2000, there have been countless news reports, lawsuits, and government and other data describing the rising toll of addiction, overdose, and death from OxyContin specifically and opioids generally.

235. In 2010, Purdue reformulated OxyContin, claiming that it would reduce tampering and make it less subject to abuse. The new OxyContin cannot be reduced to a powder as easily and does not dissolve; when water is added to it, it becomes gelatinous and cannot be injected.

236. While an important step, Purdue knew that even the reformulation of OxyContin did not resolve issues of abuse and addiction. A recent article in the LOS ANGELES TIMES revealed that Purdue – since 2002 – has kept a database of 1,800 doctors suspected of inappropriately prescribing its drugs, but Purdue did not alert law enforcement or medical authorities to all but a few of these doctors.[82] This database, according to the news report, was whittled down from 3,200 doctors reported as suspicious by Purdue's sales representatives (conduct that must have been so egregious that the sales representatives forewent the chance to earn commissions on the doctors' prescriptions).

237. Purdue did not use its database of problem doctors to reduce OxyContin abuse, to rein in dangerous doctors, or to stop the potentially unlawful distribution of a controlled substance. Instead, the company presented the evidence of rogue prescribing in an effort to persuade the FDA that generic drug makers should not be allowed to copy the earlier, non-tamper resistant version of OxyContin – the same OxyContin that Purdue originally promoted as less addictive – as it is too subject to abuse.

238. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in the LOS ANGELES TIMES article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." Instead, on information and belief, Purdue continued to

[82] Glover & Girion, *supra* note 81.

profit from the prescriptions of these suspicious prescribers. Psychologist, researcher, and Stanford University professor Keith Humphreys noted, "[t]hose doctors are a gold mine for Purdue. And the whole time they're taking the money, knowing that something is wrong, and not telling anyone until it gives them a market advantage to do so. That is really disgusting."[83]

G. Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False, Unfounded and Dangerous, and Would Harm Chicago Residents.

239. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic non-cancer pain were untrue and unproven. The history of opioids, as well as research and clinical experience over the last 20 years, established that they were deeply addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to address nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

240. Moreover, Defendants intended doctors, patients, and payers to rely on their representations. Defendants closely monitored their sales and the habits of prescribing doctors, which allowed them to see sales balloon, overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CMEs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to and also watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended –

[83] *Id.*

that their misrepresentations would persuade doctors to prescribe, patients to use, and payers to cover their opioids for chronic pain.

H. Defendants Fraudulently Concealed their Misrepresentations

241. At all times relevant to this Complaint, Defendants took steps to avoid detection of and fraudulently conceal their deceptive marketing and conspiratorial behavior.

242. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and relied on them to vouch for the accuracy and integrity of Defendants' untrue and unsupportable statements about opioid use for chronic non-cancer pain.

243. Upon information and belief, while Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Upon information and belief, Defendants exerted their considerable influence on these promotional and "educational" materials through their funding of and relationship with KOLs and front groups, both directly and through their public relations companies.

244. Contrary to their competitive interest in promoting their own opioid products, Defendants disseminated their deceptive messages through websites that were unbranded (did not promote a specific drug) and therefore could not easily be tied to a particular drug company sponsor. Unbranded messaging created the appearance of neutrality and gave Defendants' marketing messages the appearance of unbiased medical science. [redacted] Upon information and belief, Defendants, including Purdue and Janssen, ran similar websites that masked their own direct role in developing the content.

245. Upon information and belief, Defendants also obscured their participation by extensively using the public relations companies they hired to work with front groups to produce and disseminate deceptive materials.

246. Much of Defendants' deceptive marketing occurred at medical conferences and through CMEs that were open only to registered medical professionals. Therefore, the City would have had no access to or awareness of their content.

247. Further, in addition to hiding their own role in the deceptive conduct, Defendants manipulated their promotional materials to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by the City. Only in recent months have some of the KOLs whom Defendants relied upon and promoted to spread their deceptive messages acknowledged the lack of support for their positions.

248. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their marketing strategy, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that the City now assert. The City was not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the City of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

I. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to the City of Chicago and Chicago Consumers.

249. Defendants' misrepresentations prompted doctors to prescribe, patients to take, and payers to cover opioids for the treatment of chronic non-cancer pain, believing that the

benefits outweighed the risks and were better than alternative treatments. Defendants set out to overcome barriers to widespread prescribing of opioids – and succeeded – through a series of deceptive messages designed to misrepresent the benefits, risks, and superiority of opioids over other treatments.

250. Defendants' deceptive marketing caused the use of opioids to explode. National trends—trends that also buffeted Chicago—reveal the alarming rates of opioid use. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids."[84] Indeed, "[o]pioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid."[85] A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010 even though the number of office visits in which patients complained of pain did not change; prescribing of non-opioid pain medications decreased over the same time.[86] For back pain alone – one of the most common chronic non-cancer pain conditions – the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady.[87] This increase corresponds with, and was caused by, Defendants' marketing push.

251. The sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States. Scientific evidence

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[84] Marie N. Stagnitti, *Statistical Brief #235: Trends in Outpatient Prescription Analgesics Utilization and Expenditures for the U.S. Civilian Noninstitutionalized Population, 1996 and 2006*, Agency for Healthcare Research and Quality, Fig. 6 (Feb. 2009), http://meps.ahrq.gov/mepsweb/data_files/publications/st235/stat235.pdf.

[85] Deborah Grady et al., *Opioids for Chronic Pain,* 171(16) Archives of Internal Med. 1426, 1426 (Sept. 12, 2011).

[86] Matthew Daubresse et al., *Ambulatory Diagnosis & Treatment of Nonmalignant Pain in the U.S., 2000-2010,* 51(10) Med. Care, 870-878 (Oct. 2013).

[87] John N. Mafi et al., *Worsening Trends in the Mgmt. & Treatment of Back Pain,* 173(17) Journal of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled and their abuse.[88] "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."[89] Opioids are involved in 40% of fatal drug overdoses – including overdoses due to illegal drugs.[90] Contrary to Defendants' misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.[91] According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for 20% of all prescription drug overdoses.[92] In 2009, there were more than twice as many deaths from prescription opioid overdoses (15,597) than from cocaine (4,350) and heroin (3,278) put together.

252. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and

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[88] Theodore J. Cicero et al., *Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States*, 16(8) Pharmacoepidemiology and Drug Safety, 827-840 (Aug. 2007).

[89] Grady, *supra* note 85, at 1426.

[90] Margaret Warner et al., *NCHS Data Brief: Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999-2006*, Centers for Disease Control & Prevention, (Sept. 2009), www.cdc.gov/nchs/data/databriefs/db22.pdf.

[91] *Results from the 2011 Nat'l Survey on Drug Use & Health: Summary of Nat'l Findings*, U.S. Dep't of Health & Human Servs. (Sept. 2012), http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.pdf.

[92] *CDC Grand Rounds: Prescription Drug Overdoses, a U.S. Epidemic*, Centers for Disease Control & Prevention (Jan. 13, 2012), www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm.

795 non-medical users.[93] Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).[94]

253. Chicago's numbers are similarly dramatic. There have been over 1,000 emergency department visits for opioid overdoses, and over 1,200 emergency department visits involving patients who were illicitly using opioids.[95] For example, estimates of visits to the emergency department in Chicago due to the misuse and abuse of prescription painkillers have been steadily increasing, with a significant increase of 65 percent between 2004 and 2011.[96]

254. By May 2014, the State of Illinois had seventy-one Certified Opioid Treatment Programs, thirty-one of which are in the City of Chicago.[97] By way of contrast, Tennessee, whose opioid epidemic is among the worst in the nation, has only twelve.[98] Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction – buprenorphine and naltrexone – were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payers at $72.5 billion.[99]

255. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new

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[93] Wilson M. Compton, *Prescription Drug Abuse: It's Not What the Doctor Ordered*, Nat'l Inst. On Drug Abuse, (May 3, 2013), www.apa.org/about/gr/science/spin/2013/05/prescription-drug-abuse.pdf.

[94] *Nat'l Estimates of Drug-Related Emergency Dep't Visits, 2004-2011,* Substance Abuse & Mental Health Servs. Admin. (2011), *http://www.samhsa.gov/data/dawn/nations/Nation_2011_NMUP.xls.*

[95] *Metro Brief Chicago*, *supra* note 6.

[96] Substance Abuse and Mental Health Services Administration, Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits. HHS Publication No. (SMA) 13-4760, DAWN Series D-39. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[97] *Opioid Treatment Program Directory,* Substance Abuse & Mental Health Servs. Admin., http://dpt2.samhsa.gov/treatment/directory.aspx

[98] *Id.*

[99] Katz, *supra* note 30.

wave of addiction, abuse, and injury. Defendants' scheme supplied both ends of the secondary market for opioids – providing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that "substantial increases in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use."[100] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.[101]

256. A significant black market in prescription opioids also has arisen, which has not only created and supplied additional addicts, but fueled other criminal activities. According to the Chicago field division of the Drug Enforcement Administration, "Street gangs, too, have become increasingly involved in prescription drug diversion."[102]

257. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals and, in 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006; nearly 80% of those who used heroin in the past year previously abused prescription opioids.[103] Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street." In the words of one federal Drug Enforcement Agency official, "Who would have ever thought in this country it would be cheaper to buy heroin than pills and obtain them more easily. That is the reality we're facing."[104]

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[100] G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) The Journal of the Am. Med. Ass'n, 1865-1866 (Nov. 14, 2012).

[101] Katz, *supra* note 30.("The most common source of abused [opioids] is, directly or indirectly, by prescription.").

[102] Thomas, *supra* note 9.

[103] NPR Staff, *With Rise of Painkiller Abuse, A Closer Look At Heroin*, NPR (Nov. 2, 2013), www.npr.org/2013/11/02/242594489/with-rise-of-painkiller-abuse-a-closer-look-at-heroin.

[104] Matt Pearce & Tina Susman, *Philip Seymour Hoffman's death calls attention to rise in heroin use*, Los Angeles Times (Feb. 3, 2014), http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204.

258. That reality holds in Chicago. Area drug treatment centers treat a significant number of patients for opioid addiction. Many of those addicted to opioids who seek treatment in Chicago treatment centers started with one prescription, liked how opioids made them feel, and stayed on them. Eventually, they became addicted, often after just a few months on opioids. Those who seek treatment often do so after a precipitating life event—either losing a job or being confronted by family—or after turning to criminal activity such as prostitution and theft to sustain their addiction. If their fates are consistent with patterns nationally some of them will overdose – some fatally, some not. Others will die prematurely from related causes – falls, traffic accidents, or assaults or from premature heart or neurological disease that hastens their death by 10 or 20 years. Those who do not relapse face a lifetime of treatment, including prolonged counseling or reliance on maintenance drugs such as methadone or buprenorphine.

259. The overprescribing of opioids for chronic non-cancer pain has given young children access to opioids, nearly all of which were prescribed for adults in their household. One study documented over 9,000 children nationally exposed to prescription opioids, with a median age of two years old. The number of exposures in young children was correlated to the number of prescriptions in the area.[105]

260. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS") also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born. They cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit

[105] . J. Elise Bailey et al., *The under recognized toll of prescription opioid abuse on young children*, 53(4) Annals of Emergency Med., 419-424 (Apr. 2009).

disorder, lack of impulse control, and a higher risk of future addiction.[106] When untreated, NAS can be life-threatening.[107] In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.[108] According to data from Tennessee, which has most closely studied the issue, 52% of mothers of NAS newborns used only drugs prescribed to them; another 20% used a mix of their own prescriptions and illicitly obtained drugs.[109]

J. Defendants' Fraudulent and Deceptive Marketing of Opioids Caused False Claims for Payment to Be Submitted to the City

261. The City provides comprehensive health care protection, including prescription drug benefits, to its employees and retirees. These benefits are provided under various health plans that the City self-insures, including a preferred provider organization ("PPO"), a health maintenance organization ("HMO"), and a plan that covers retirees who are not yet on Medicare and provides supplemental coverage to those retirees who are on Medicare. The prescription drug plan under the PPO is self-insured: the costs of prescription drugs are passed on directly to the City, which reimburses the plans for any prescription costs the plans incur. Throughout the relevant time period for this action, the PPO's prescription drug costs have been passed on directly to, and paid by, the City.

262. The HMO's prescription drug coverage has been self-insured at various times throughout the relevant time period. Before July 2006, the City paid the premiums for the HMO plans, which in turn covered the cost of prescription drugs. Between July 2006 and December 2009, the City paid the premiums for the HMO plan to Unicare, which in turn covered the cost of

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[106] *Transcript of Impact of Approved Drug Labeling – Part 15 Hearing* at 116-121, F.D.A. (Feb. 7, 2013), www.fda.gov/downloads/Drugs/NewsEvents/UCM342700.pdf.

[107] *See* Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation & Research, to Petitioner, Nat'l Advocates for Pregnant Women (Apr. 16, 2014).

[108] Stephen W. Patrick et al., *Neonatal Abstinence Syndrome & Associated Health Care Expenditures*, 307(18) Journal of the Am. Med. Ass'n 1934, 1937 (May 9, 2012).

[109] Jonel Aleccia, *'Just flooding us': Tenn. spike in drug-dependent newborns is warning to nation*, NBC News (Oct. 11, 2013), *http://www.nbcnews.com/health/kids-health/just-flooding-us-tenn-spike-drug-dependent-newborns-warning-nation-f8C11375654.*

prescription drugs, but during that same time period, the City also had an HMO with Blue Cross/Blue Shield, which passed the costs of prescriptions drugs directly on to the City. From January 2010 to December 2011, both HMO plans were operated by Blue Cross/Blue Shield and the costs of prescriptions drugs were paid directly by the City. From January 2012 to December 2013, two HMO plans were merged into one HMO plan and the City paid premiums to the HMO plan, which in turn covered the cost of prescription drugs. Since January 1, 2014, the City's prescription drug coverage under the HMO is once again self-insured and has been directly paying the costs of prescription drugs under the HMOs.

263. The City's self-insured health plans only cover the cost of prescription drugs that are "Medically Necessary" and dispensed for a FDA-approved purpose. Prescription drugs that are not "Medically Necessary" or that are dispensed for a non-FDA-approved purpose are expressly excluded from coverage under the City's plans. Under the plans, a "Medically Necessary" prescription is that which is "customary for the treatment or diagnosis of an Illness or Injury, and is consistent with generally accepted medical standards."

264. Defendants specifically targeted doctors with their fraudulent marketing efforts in an effort to persuade doctors that opioids have real benefits and minimal risks and are superior to alternate treatments. Doctors relied in good faith on Defendants' false representations to prescribe opioids for chronic non-cancer pain, and Defendants reaped the benefits of increased opioid sales and profits.

265. In Chicago, Defendants' fraudulent marketing prompted doctors to prescribe opioids for chronic non-cancer pain to patients covered by the City's health plans. Doctors were and are bound by the provider agreements that entitle them to participate in the City's health plans. These agreements permit doctors to charge only for services that are "medically necessary," which requires that treatments be "in accordance with generally accepted standards of medical practice," and "clinically appropriate . . . and considered effective for the patient's illness, injury or disease." Generally accepted standards of medical practice is defined in the agreement as standards "based on credible scientific evidence."

266. Doctors submit claims directly to the City's health plan for the costs associated with prescribing opioids, including office visits and toxicology screens for patients prescribed opioids. In addition, prescriptions for opioids for patients covered by the City's self-insured health plans are filled by pharmacies, which submit claims for reimbursement to the City's health plan. In prescribing and filling prescriptions for chronic opioid therapy, doctors and pharmacists expressly and impliedly certify the prescriptions as "Medically Necessary," and—at least with respect to the self-insured plans (the PPO, and the various self-insured HMOs)—the health plans authorize payment from City funds.

267. But as the scientific evidence makes clear, opioid treatments for chronic non-cancer pain are not "Medically Necessary" as the City health plans define that term: Opioid treatment for chronic non-cancer pain is not a customary treatment, not consistent with generally accepted medical standards, not effective, and not based on credible scientific evidence.

268. Defendants' fraudulent marketing scheme also caused the City to pay for opioids for non-FDA approved purposes. Cephalon's Fentora, for example, was specifically marketed for non-FDA approved uses. Physicians, in turn, wrote prescriptions for Fentora for non-FDA approved uses, causing the self-insured health plans to authorize and the City to pay for those prescriptions. A review of City records reveals that opioids were prescribed for other non-FDA approved uses, including depression.

269. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by the deceptive marketing of Defendants, as laid out above; Defendants' ability to seed—through fraud—medical practice that supported the use of opioids for chronic non-cancer pain should not entitle them to profit from that fraud.

270. Defendants' fraudulent marketing scheme also caused the City to pay for opioid treatments that were worthless. Not only did chronic opioid therapy often provide no benefit in treating chronic long term pain or improving patients' function, it often worsened the pain and subjected patients to significant risks and adverse effects.

271. Since 2007, the City has paid—just in the PPO plan alone—nearly 400,000 claims submitted to it for the payment of opioid prescription fills with a total cost to the City of nearly $9,500,000. As a 2008 presentation to the FDA by the Group Health Research Institute made clear, 87% of all opioids dispensed were to chronic pain patients using opioids long-term, whereas only 13% were for acute or cancer pain patients.[110] Based on this, and upon information and belief, approximately 87% of the opioid fills that the City has paid for have been for non-"Medically Necessary" and/or non-FDA approved uses.

272. Although Defendants' collective promotion led to the total City spend on opioids, the City has spent substantial sums on each Defendant's opioids. Just from the PPO and just since 2007, the City has paid 7,949 claims, totaling $2,548,497.99 for Purdue opioids; 172,438 claims, totaling $1,553,867.3 for Actavis opioids; 2,559 claims, totaling $701,971.35 for Endo opioids; 1,564 claims, totaling $272,440.90 for Janssen opioids; and 105 claims, totaling $139,640.65 for Cephalon opioids. These figures do not reflect the cost to the City of other opioid prescriptions caused by Defendants' marketing or other costs laid out in Section I, below.

K. Defendants' Fraudulent and Deceptive Marketing of Opioids Has Caused the City to Incur Related Costs

273. In addition to paying for the costs of filling opioid prescriptions pursuant to its employee and retiree health plans, the City has suffered significant additional damages as a result of the Defendants' deceptive promotion. The City and its health plans have paid costs that include, but are not limited to, the costs immediately associated with prescribing opioids, such as doctors' visits and toxicology screens to monitor patients' drug-taking, as well as other costs imposed by long-term opioid use, abuse, and addiction, such as hospitalizations for opioid overdoses, drug treatment for individuals addicted to opioids, intensive care for infants born addicted to opioids, and more. In addition, Defendants have imposed upon the City costs beyond

[110] *See* Von Korff, *supra* note 5.

its health plans, providing emergency services, funding addiction treatment, and paying other costs imposed by the epidemic of opioid use and abuse in the City.

VI. COUNT ONE

CONSUMER FRAUD

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 2-25-090 AGAINST ALL DEFENDANTS

274. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

275. The Chicago Municipal Code § 2-25-090 makes it unlawful for a business to "engage in any act of consumer fraud, unfair method of competition, or deceptive practice while conducting any trade or business in the city," including "any conduct constituting an unlawful practice under the Illinois Consumer Fraud and Deceptive Business Practices Act." The Illinois Consumer Fraud and Deceptive Business Practices Act, 735 ILCS 505/2, makes unlawful, among other things, "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' . . ."

276. Defendants have engaged in unlawful, deceptive, and unfair business practices in violation of the Municipal Code as set forth above.

277. Defendants' practices as described in the Complaint are deceptive business practices that violate Chicago Municipal Code § 2-25-090 because the practices were and are intended to deceive consumers and occurred and continue to occur in the course of conduct involving trade and commerce in the City.

278. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 2-25-090 by making and disseminating untrue, false, and misleading statements to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic non-cancer pain.

279. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 2-25-090 by making statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic non-cancer pain.

280. Defendant Purdue made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;
- Posting on the internet misleading statements and pamphlets concerning the risk of addiction and the misleading concept of pseudoaddiction;
- Distributing brochures to doctors that included misleading statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributed and assisted in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Endorsing and assisting in the distribution of CME programs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the dissemination of scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and
- Exclusively disseminating misleading statements in education materials to Chicago hospital doctors and staff while purportedly educating them on new pain standards created by JCAHO.

281. Defendant Endo made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, controlling, endorsing and sponsoring patient education materials and programs that contained misleading statements;
- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the ability of opioids to improve function long-term, and the efficacy of opioids long-term, in the treatment of chronic non-cancer pain;
- Facilitating the posting on the internet of misleading statements and pamphlets concerning the risk of addiction, the misleading concept of pseudoaddiction and misleading claims that long-term treatment of opioids improves function;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations – including over $10 million to the organization responsible for many of the most egregious misrepresentations – that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting the in the dissemination of literature written by pro-opioid KOLs that contained false, misleading and untrue statement concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the dissemination of scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life; and
- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain.

282. Defendant Janssen made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, controlling, endorsing and sponsoring patient education materials and programs that contained misleading statements concerning the risk of addiction;
- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the efficacy of opioids long-term in the treatment of chronic non-cancer pain;

- Facilitating the posting of misleading statements and pamphlets, concerning the risk of addiction, the misleading concept of pseudoaddiction and misleading claims that long-term treatment of opioids improves function;

- Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain in the elderly;

- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeted the elderly in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain in the elderly; and

- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain.

283. Defendant Cephalon made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, endorsing and sponsoring patient education materials that contained misleading statements;

- Endorsing, directly distributing and assisting in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CME programs containing untrue, false and misleading statements concerning the use of opioids approved only for cancer pain to treat chronic non-cancer pain, and which did not concern cancer pain;

- Assisting in the dissemination of scientific studies that misleadingly concluded Cephalon's opioids (approved only for cancer pain) are safe and effective for the long-term treatment of chronic non-cancer pain; and

- Targeting its marketing to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists and workers' compensation programs serving chronic pain patients.

284. Defendant Actavis made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;

- Instructing its sales force to make false, misleading and untrue statements to doctors concerning the ability of opioids to improve function long-term, in the treatment of chronic, non-cancer pain.

- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the risk of addiction in the long-term treatment of chronic, non-cancer pain.

- Providing significant financial support to pro-opioid key opinion leader who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain.

285. Defendants knew at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and therefore likely to deceive the public. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks of opioids.

286. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids untrue, false, and misleading. In omitting and concealing these material facts, Defendants intended to cause Chicago consumers and payers of opioid prescriptions to rely on those omissions and concealments.

287. All of this conduct, separately and collectively, was intended to deceive Chicago consumers who used or paid for opioids for chronic non-cancer pain, Chicago physicians who prescribed opioids for chronic non-cancer pain, and Chicago payers, including the City, who purchased, or covered the purchase of, opioids for chronic non-cancer pain.

288. Defendants' practices as described in the Complaint are also unfair practices that violated Chicago Municipal Code § 2-25-090 because the practices offend public policy; are immoral, unethical, oppressive, or unscrupulous; or caused substantial injury to consumers.

289. Defendants' practices in deceptively exaggerating the benefits and minimizing the risks of these addictive drugs offend deep-seated public policies aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs, and preventing addiction and the sale and use of illegal drugs, among others, as described above. Defendants have sacrificed their duties to their customers and to public health in favor of blockbuster profits. They have caused and continue to cause grievous harm to consumers. The staggering rates of opioid use, abuse, and addiction resulting from Defendants' marketing efforts have caused substantial injury, including, but not limited to:

a. Upwards of 30% of all adults have used opioids, with the vast majority of the use stemming from prescribing for chronic non-cancer pain conditions. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Children, too, have been harmed by opioids. They have been exposed to medications prescribed to family members or others, resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among Chicago teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and potentially lasting developmental impacts.

c. Chicagoans who have never taken opioids also have also been injured. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. More broadly, opioid use and misuse have driven Chicagoans' health care costs higher.

e. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

f. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process.

g. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids have increased the demands on emergency services and law enforcement in the City.

h. All of this has caused substantial injuries to consumers – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes.

290. Defendants' practices have also violated Chicago Municipal Code § 2-25-090 because the practices violate the Illinois Consumer Fraud and Deceptive Business Practices Act, which is incorporated into the Chicago Municipal Code § 2-25-090 by reference. The Illinois Consumer Fraud and Deceptive Business Practices Act makes unlawful, among other things, "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' . . ." 735 ILCS § 505/2.

291. Defendants' employed several practices proscribed by the Uniform Deceptive Trade Practices Act:

292. By, among other things, using front groups, KOLs, and others to peddle their misrepresentations, by influencing the creation of misleadingly pro-opioid treatment guidelines and CMEs, and by distorting the scientific evidence for opioid use for chronic non-cancer pain, Defendants made it appear that opioids had sponsorship and qualities that opioids do not have. In so doing, Defendants:

- "cause[d] likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services." 735 ILCS § 510/2(a)(2).

- "cause[d] likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another." 735 ILCS § 510/2(a)(3).
- "represent[ed] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have." 735 ILCS § 510/2(a)(5).

293. By, among other things, deceptively characterizing the risks of NSAIDs in order to promote opioids, Defendants "disparage[d] the goods, services, or business of another by false or misleading representation of fact." 735 ILCS § 510/2(a)(8).

294. Altogether, Defendants "engage[d] in any other conduct which similarly creates a likelihood of confusion or misunderstanding." 735 ILCS § 510/2(a)(12).

295. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and/or other benefits, which they would not have received if they had not engaged in the violations of Chicago Municipal Code § 2-25-090 as described in this Complaint.

296. By reason of the Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count One of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 2-25-090; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' consumer fraud, unfair competition, and deceptive practices; (d) compelling Defendants to pay civil penalties up to $10,000 per violation pursuant to § 2-25-0909(f) for each day the violations occurred; (e) compelling Defendants to disgorge their ill-gotten profits; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

VII. COUNT TWO

MISREPRESENTATIONS IN CONNECTION WITH SALE OR ADVERTISEMENT OF MERCHANDISE

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 4-276-470 AGAINST ALL DEFENDANTS

297. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

298. Section 4–276–470(1) of the Chicago Municipal Code states:

> It shall be unlawful for any person to act, use or employ any deception, fraud, false pretense, false promise or misrepresentation, or to conceal, suppress or omit any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale * * * or advertisement of any merchandise.

299. Defendants' practices as described in the Complaint violated Chicago Municipal Code § 4-276-470(1) because the practices were intended to deceive doctors, consumers, and other health care payers and occurred in connection with sale or advertisement of any merchandise.

300. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 4-276-470(1) by making and disseminating deceptions and misrepresentations to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic non-cancer pain.

301. Defendants knew at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and failed to disclose material risks and were therefore likely to deceive doctors, consumers, and other health care payers. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks of opioids.

302. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids untrue, false, and misleading. In

omitting and concealing these material facts, Defendants intended to cause Chicago doctors, consumers, and other payers of opioid prescriptions to rely on those omissions and concealments.

303. All of this conduct, separately and collectively, was intended to deceive Chicago consumers who used or paid for opioids for chronic non-cancer pain, Chicago physicians who prescribed opioids for chronic non-cancer pain, and other payers, including the City, who purchased, or covered the purchase of, opioids for chronic non-cancer pain.

304. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of Chicago Municipal Code § 4-276-470(1) as described in this Complaint.

305. By reason of the Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Two of the Complaint; Chicago Municipal Code(b) compelling Defendants to pay civil penalties up to $2000 per violation pursuant to § 4-276-480 for each day the violations occurred; and (c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

VIII. COUNT THREE

FALSE STATEMENTS TO THE CITY

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-21-010, *ET SEQ.* AGAINST ALL DEFENDANTS

306. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

307. Section 1-21-010(a) of the Chicago Municipal Code provides, in pertinent part:

> Any person who knowingly makes a false statement of material fact to the city in violation of any statute, ordinance or regulation, or who knowingly makes a false statement of material fact to the city in connection with any application, report,

> affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit, is liable to the city for a civil penalty of not less than $500.00 and not more than $1,000.00, plus up to three times the amount of damages which the city sustains because of the person's violation of this section. A person who violates this section shall also be liable for the city's litigation and collection costs and attorney's fees. The penalties imposed by this section shall be in addition to any other penalty provided for in the municipal code.

308. Section 1-21-010(d) of the Chicago Municipal Code provides, in pertinent part, that:

> For the purposes of Chapter 1-21 of this Code, a person knowingly makes a false statement of material fact when that person (i) makes a statement of material fact with actual knowledge that the statement was false, or (ii) makes a statement of material fact with knowledge of facts or information that would cause a reasonable person to be aware that the statement was false when it was made, or (iii) signs, certifies, attests, submits or otherwise provides assurances, or causes any other person to sign, certify, attest, submit or otherwise provide assurances, that a statement of material fact is true or accurate in deliberate ignorance or reckless disregard of the truth or falsity of the statement. For purposes of this section, a person who fails to make a reasonable investigation to determine the accuracy, truthfulness or completeness of any material fact acts in deliberate ignorance or reckless disregard of the truth or falsity of the material fact.

309. Subsection 1-21-020 of the Chicago Municipal Code provides, in pertinent part, that:

> Any person who aids, abets, incites, compels or coerces the doing of any act prohibited by this chapter shall be liable to the city for the same penalties for the violation.

310. Defendants have incited or caused others to submit false statements of material fact to the City. Through their scheme to illegally and deceptively promote opioids in an effort to further opioids sales, Defendants aided, abetted, incited, or caused doctors, pharmacists, and/or agents of the health plans to sign, certify, attest, submit or otherwise provide assurances, expressly or impliedly, that opioids to treat chronic non-cancer pain were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain.

311. If the City had known of the false statements disseminated by Defendants in support of opioids and that doctors, pharmacists, and/or agents of the health plan were certifying and/or determining that opioids were "medically necessary" based on those false statements, the City would have refused to authorize payment for opioid prescriptions.

312. By virtue of the above-described acts, Defendants aided, abetted, incited, and caused others to make false statements of material fact to the City in connection with claims to pay for opioids to treat chronic pain, within the meaning of Chicago Municipal Code § 1-21-010 and 1-21-020.

313. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Three of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-010 and/or 1-21-020; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' false statements; (d) compelling Defendants to pay civil penalties up to $1,000 for each false statement made to the City that the Defendants aided, abetted, incited, or caused; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

IX. COUNT FOUR

FALSE CLAIMS

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-22-020 AGAINST ALL DEFENDANTS

314. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

315. Section 1-22-020 of the Chicago Municipal Code is violated when any person "(1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the city; [or] (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid."

316. Section 1-22-010 of the Chicago Municipal Code defines a claim as "any request or demand, whether under a contract or otherwise, for money or property which is made by a city contractor, grantee, or other recipient if the city is the source of any portion of the money or property which is requested or demanded, or if the city will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded."

317. Defendants, through their deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used a false statement to get a false or fraudulent claim for payment or approval by the City.

318. Defendants knew, or by the exercise of reasonable care should have known, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting the City's health plans and other insurers to reimburse or pay for opioids. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic non-cancer pain.

319. The Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic non-cancer pain that were presented to the City's health plans for payment. The City

only covers the cost of prescription drugs that are "medically necessary." Opioids, however, are not "medically necessary" to treat chronic non-cancer pain. Yet doctors, pharmacists, and/or other agents of the health plans, expressly or impliedly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the City were for uses that were not approved by the FDA and therefore, were not medically necessary.

320. Defendants knew or should have known that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic non-cancer pain, which were dispensed as a consequence of Defendants' fraud.

321. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants and that doctors, pharmacies, and/or the health plans were certifying and/or determining that opioids were medically necessary, the City would have refused to authorize payment for opioid prescriptions.

322. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic non-cancer pain were paid by the City.

323. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City to approve and pay such false and fraudulent claims.

324. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

325. Defendants' fraudulent marketing scheme also caused the City to pay false claims in that the scheme also caused the City to pay for opioids that were worthless. As described

above, opioids provide no benefit to many patients treated with them long-term for chronic pain; in many cases, it worsened the pain and subjected patients to significant risks and adverse effects.

326. The City, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

327. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

328. Each Defendant is responsible for the claims submitted and the amount the City spent on each Defendant's opioids.

329. Because Defendants acted concurrently and/or collaboratively in carrying out a common fraudulent scheme—causing others to submit false claims for opioids which were paid by the City—Defendants are jointly and severally liable for the City's total spend on non-medically necessary opioids to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Four of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-020; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' false statements; (d) compelling Defendants to pay civil penalties up to $10,000 for each false or fraudulent claim the Defendants caused to be presented to an official or employee of the City for payment or approval; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including

attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

X. COUNT FIVE

CONSPIRACY TO DEFRAUD BY GETTING FALSE OR FRAUDULENT CLAIMS PAID OR APPROVED BY THE CITY

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-22-020 AGAINST ALL DEFENDANTS

330. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

331. Section 1-22-020 of the Chicago Municipal Code is violated when any person "(1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the city; [or] (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid."

332. Defendants conspired to defraud the City by getting a false or fraudulent claims allowed or paid, by acting in concert in a comprehensive scheme to defraud the City while illegally and deceptively promoting opioids in an effort to further opioids sales.

333. Defendants knowingly and voluntarily engaged in a concerted scheme to promote the widespread use of opioids for the treatment of chronic non-cancer pain directly through their own publications and employees, and indirectly, through seemingly independent thought-leaders, advocacy groups, and professional societies, by making, funding, suggesting, editing, approving, and distributing untrue, false, and misleading statements and representations to doctors and patients. The concerted scheme was entered into for the purpose of getting insurers, including the City's health plans, to reimburse or pay for opioids.

334. Defendants' common scheme was carried out through their common funding of the same front groups, CMEs and KOLs, their common advocacy through and participation in the Pain Care Forum, their coordinated marketing messages, and other steps.

335. Because of the Defendants' scheme, doctors wrote prescriptions for opioids to treat chronic non-cancer pain that were submitted to the City's health plans for payment, which only covers the cost of "medically necessary" prescriptions and those that are prescribed for FDA-approved uses. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain. Yet doctors, pharmacists, and/or other agents of the health plans explicitly or implicitly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the City were for uses that were not approved by the FDA and therefore were not medically necessary.

336. Defendants knew or should have known that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic non-cancer pain, which were dispensed as a consequence of Defendants' fraud.

337. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants in support of opioids and that doctors, pharmacies, and/or the health plans were certifying and/or determining that opioids were medically necessary based on those false statements, the City would have refused to authorize payment for opioid prescriptions.

338. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic non-cancer pain were paid by the City.

339. By virtue of the above-described acts, Defendants conspired to defraud the City by getting a false or fraudulent claim allowed or paid.

340. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

341. Defendants' fraudulent marketing scheme also caused the City to pay false claims in that the scheme also caused the City to pay for opioids that were worthless. As described above, opioids provide no benefit to many patients treated with them long-term for chronic pain; in many cases, it worsened the pain and subjected patients to significant risks and adverse effects.

342. The City, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

343. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

344. Each Defendant is responsible for the claims submitted and the amount the City spent on each Defendant's opioids.

345. Because Defendants acted concurrently and/or collaboratively in carrying out a common fraudulent scheme—causing others to submit false claims for opioids which were paid by the City—Defendants are jointly and severally liable for the City's total spend on non-medically necessary opioids to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Five of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-020; (c) compelling Defendants to pay restitution of any money acquired by Defendants' false statements; (d) compelling Defendants to

pay civil penalties up to $10,000 for each instance Defendants made or used false records and statements and caused false statements and records to be used to get a false or fraudulent claim paid or approved by the City; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (f) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XI. COUNT SIX

RECOVERY OF CITY COSTS OF PROVIDING SERVICES VIOLATIONS OF THE CHICAGO MUNICIPAL CODE § 1-20-020 AGAINST ALL DEFENDANTS

346. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

347. Section 1-20-020 of the Chicago Municipal Code provides, in pertinent part:

> Any person who causes the city or its agents to incur costs in order to provide services reasonably related to such person's violation of any federal, state or local law, or such person's failure to correct conditions which violate any federal, state or local law when such person was under a legal duty to do so, shall be liable to the city for those costs. This liability shall be collectible in the same manner as any other personal liability.

348. The defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

(1) violating Chicago Municipal Code § 2-25-090;

(2) violating Chicago Municipal Code § 4-276-470;

(3) violating Chicago Municipal Code § 1-21-010;

(4) violating Chicago Municipal Code § 1-22-020;

(5) violating Chicago Municipal Code § 1-20-020;

(6) violating 720 ILCS § 5/17-10.5;

(7) committing common law fraud; and

(8) committing common law unjust enrichment.

349. The City has incurred costs reasonably related to Defendants' violations of federal, state, or local laws.

350. The City has incurred the costs of paying for opioids prescribed for chronic non-cancer pain and related costs through its health plans, and these costs are reasonably related to Defendants' unlawful scheme.

351. The City's health plans have paid costs that include, but are not limited to, the costs immediately associated with prescribing opioids, such as doctors' visits and toxicology screens to monitor patients' drug-taking, as well as other costs imposed by long-term opioid use, abuse, and addiction, such as hospitalizations for opioid overdoses, drug treatment for individuals addicted to opioids, intensive care for infants born addicted to opioids, and more. In addition, Defendants have imposed upon the City costs beyond its health plans, such as providing emergency services, funding addiction treatment, and paying other costs imposed by the epidemic of opioid use and abuse in the City.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Six of the Complaint; (b) compelling Defendants to pay the costs the City incurred that were reasonably related to the Defendants' violations of federal, state, or local law; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XII. COUNT SEVEN

INSURANCE FRAUD VIOLATIONS OF 720 ILCS 5/17-10.5 AGAINST ALL DEFENDANTS

352. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

353. 720 ILCS § 5/17-10.5(a)(1) provides in pertinent part:

> (1) A person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false

> claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.

354. 720 ILCS § 5/17-10.5(e)(1) provides in pertinent part:

> Civil damages for insurance fraud. A person who knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of any insurance company by the making of a false claim or by causing a false claim to be made on a policy of insurance issued by an insurance company, or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property, shall be civilly liable to the insurance company or self-insured entity that paid the claim or against whom the claim was made or to the subrogee of that insurance company or self- insured entity in an amount equal to either 3 times the value of the property wrongfully obtained or, if no property was wrongfully obtained, twice the value of the property attempted to be obtained, whichever amount is greater, plus reasonable attorney's fees.

355. Through their illegal and deceptive promotion of opioids, Defendants knowingly caused false claims to be made to the City's health plans, which are self-insured, and knowingly obtained or caused to be obtained through deception the property of the City in payments for those false claims.

356. The Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic non-cancer pain that were presented to the City's health plans, which cover City employees and retirees, for payment.

357. Further, the City only covers the cost of services, tests, and prescription drugs that are "medically necessary" and prescribed for an FDA-approved use. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain.

358. Doctors, pharmacists, or other agents of the health plans, explicitly or implicitly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the

City were for uses that were not approved by the FDA and therefore, were not medically necessary.

359. The misrepresentations were material because if the City had known of the false statements disseminated by Defendants and that doctors, pharmacies, and/or the health plans certified and/or determined that opioids were medically necessary based on those false statements, the City would have refused to authorize payment for opioid prescriptions. The City is a self-insured entity and directly covers the cost of prescription drugs for City employees and retirees.

360. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made false claims with the intent to induce the City to approve and pay such false and fraudulent claims.

361. By reason of Defendants' insurance fraud, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription to be filled, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Seven of the Complaint; (b) compelling Defendants to pay three times any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XIII. COUNT EIGHT

CIVIL CONSPIRACY
VIOLATIONS OF THE COMMON LAW PROHIBITION AGAINST CIVIL CONSPIRACY
AGAINST ALL DEFENDANTS

362. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

363. Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

364. Defendants' common scheme was carried out through their common funding of the same front groups, CMEs and KOLs, their common advocacy through and participation in the Pain Care Forum, their coordinated marketing messages, and other steps.

365. The defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

(1) violating Chicago Municipal Code § 2-25-090;

(2) violating Chicago Municipal Code § 4-276-470;

(3) violating Chicago Municipal Code § 1-21-010;

(4) violating Chicago Municipal Code § 1-22-020;

(5) violating Chicago Municipal Code § 1-20-020;

(6) violating 720 ILCS § 5/17-10.5;

(7) committing common law fraud; and

(8) committing common law unjust enrichment.

366. By reason of the Defendants' unlawful acts, the City has been damaged and continues to be damaged by paying for the costs of opioid prescriptions for chronic non-cancer pain and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Eight of the Complaint; (b) compelling Defendants to pay the City's direct and consequential damages; and

(c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XIV. COUNT NINE

COMMON LAW FRAUD AGAINST ALL DEFENDANTS

367. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

368. Defendants made false statements of material fact that they knew were false to induce the City to act; the City relied on Defendants' false statements, relied on others who relied on Defendants' false statements, or both; and was damaged as a result.

369. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' and seemingly truthful statements about opioids untrue, false, and misleading. In omitting and concealing these material facts, Defendants intended to cause Chicago consumers and payers of opioid prescriptions to rely on those omissions and concealments.

370. Defendants engaged in this scheme because they intended prescription drug payers, including the City, to rely on its statements about the safety and efficacy of opioids and rely on its omissions about the risks of opioids.

371. The City relied on Defendants' statements or relied on others who relied on Defendants' statements about the risks, benefits, and superiority of opioids for the treatment of chronic non-cancer pain when it paid for prescriptions for opioids to treat chronic non-cancer pain. Had the City known about the false statements disseminated by Defendants in support of opioids for chronic non-cancer pain, the City would have refused to authorize payment for such opioid prescriptions.

372. By reason of the Defendants' fraud, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000, and suffered

additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Nine of the Complaint; (b) compelling Defendants to pay restitution of any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; (d) compelling Defendants to pay punitive damages because their false representations were wantonly and designedly made; and (e) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XV. COUNT TEN

UNJUST ENRICHMENT

VIOLATIONS OF THE COMMON LAW PROHIBITION ON UNJUST ENRICHMENT AGAINST ALL DEFENDANTS

373. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

374. Defendants have unjustly retained a benefit to the City's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

375. By illegally and deceptively promoting opioids, Defendants have unjustly enriched themselves at the City's expense. The City has made payments for opioid prescriptions and treatments, and Defendants benefited from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the City lacks a remedy provided by law.

376. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Ten of the

Complaint; (b) compelling Defendants to disgorge all unjust enrichment to the City; and (c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

DATED: June ___, 2014.

Respectfully submitted,

STEPHEN R. PATTON
Corporation Counsel, City of Chicago

BY: _____

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IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CITY OF CHICAGO,

a municipal corporation,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; and ACTAVIS PLC,

Defendants.

Case No.: 2014L005854

FILED
2014 JUN 30 PM 5:27

PLAINTIFF CITY OF CHICAGO'S MOTION FOR LEAVE TO INITIALLY FILE AN UNREDACTED COMPLAINT UNDER SEAL WITH A REQUEST THAT THE COURT, AFTER DUE REVIEW, ENTER AN ORDER UNSEALING THE UNREDACTED COMPLAINT

Plaintiff, City of Chicago ("City"), has filed a redacted Complaint ("Complaint") alleging that Defendants (as hereinafter defined) have engaged in an unlawful campaign of deception in their marketing of opioid drugs ("Opioids"). The Complaint redacts references to documents that were previously produced to the City and designated by the producing parties as confidential pursuant to applicable confidentiality agreements and/or a protective order, as further explained below. The City now moves to file an unredacted copy of the Complaint under seal ("Sealed Complaint"). Because the City does not believe that the documents or information designated as confidential are in fact confidential, the City further requests that this Court—after allowing the Sealed Complaint to be filed—review the Sealed Complaint in camera, determine that the redacted information is not confidential, and issue an order unsealing the Sealed Complaint.

STANDARD OF REVIEW

1. There is a strong presumption in favor of public access and against sealing complaints. *Skolnick v. Altheimer & Gray*, 191 Ill. 2d 214, 230, 730 N.E.2d 4, 15 (2000). "[W]hether court records in a particular case are opened to public scrutiny rests with the trial court's discretion, which must take into consideration all facts and circumstances unique to that case." *Id.* at 231 (citing *Nixon v. Warner Commc'n, Inc.*, 435 U.S. 589, 579 (1978)); *see also In re Marriage of Johnson*, 232 Ill.App.3d 1068, 1072–73, 598 N.E.2d 406 (1992) (to overcome the presumption of access, the moving party bears the burden of establishing a compelling interest why access should be restricted and that the protective order is drafted in the manner least restrictive of the public's interest).

2. The redacted information does not contain any proprietary or commercially sensitive information, and the public interest in unsealing this information outweighs the Defendants self-serving confidential designations.

BACKGROUND

The City's Pre-Suit Investigation

3. The City, by and through Stephen R. Patton, Corporation Counsel for the City, pursuant to its authority under the City's False Claims ordinance, Chicago Municipal Code § 1-22-050, engaged in a thorough, year-long investigation into the marketing of opioids for chronic pain, (the "Investigation"). As a result of this Investigation, the City has concluded that Defendants have engaged in illegal conduct, in violation of several local and state laws. To remedy their past conduct and prevent future unlawful conduct, the City filed its ten-count Complaint against defendants Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, Ltd. ("Teva"); Cephalon, Inc.; Johnson &

Johnson; Janssen Pharmaceuticals, Inc. ("Janssen"); Endo Health Solutions Inc. ("Endo"); and Actavis plc ("Actavis") (collectively, "Defendants").

The Confidentiality Agreements

4. During the course of the Investigation, the City used various investigatory tools, including its subpoena powers under Chicago Municipal Code § 1-22-050 (City's False Claims Ordinance"). Several of the now-Defendants, among other subpoena recipients, resisted the City's subpoenas. In an effort to move the Investigation along, the City agreed to enter into: (a) a Confidentiality Stipulation and Protective Order with defendant Janssen ("Janssen Order"), (b) written confidentiality agreements with defendants Actavis ("Actavis Agreement") and Teva ("Teva Agreement"), and (c) an informal oral confidentiality agreement with Endo that was never reduced to writing ("Endo Agreement"). Copies of the various documents are attached hereto as **Exhibit A** (Janssen), **Exhibit B** (Actavis), **Exhibit C** (Teva), and **Exhibit D** (Endo), respectively. The City also entered into a confidentiality agreement with non-defendant subpoena respondent American Pain Foundation ("APF Agreement"), a copy of which is attached hereto as **Exhibit E**. (The Janssen Order, Actavis Agreement, Teva Agreement, Endo Agreement, and APF Agreement are herein after collectively referred to as the "Confidentiality Agreements.")

5. The Confidentiality Agreements provided that "confidential" or "protected" information ("Confidential Information")—defined as any information that contains trade secrets, proprietary or commercially sensitive information[1]—would not be disclosed by the City.

[1] The Janssen Order defines "Confidential Information" as information containing "trade secrets, proprietary or commercially sensitive information (including information defined as 'trade secrets' in the Illinois Trade Secrets Act, 765 ILCS 1065), or Protected Health Information as such term is defined in 45 C.F.R.§ 160.13 ('Protected Information')." Ex. A ¶ 3. The Actavis Agreement defines a Protected Document as one that is "confidential, proprietary or otherwise

Moreover, as discussed further below, the various agreements provide that any documents that were produced to the City with confidential designations would be treated as confidential by the City. The Actavis Agreement, for example, states that "Except as otherwise indicated below, documents marked or otherwise designated as 'Confidential' that are produced or made available for inspection and copying by Actavis to the City of Chicago's attorneys, consultants, agents, or experts shall be Protected Documents and given confidential treatment as described in the Agreement." Ex. B ¶ 1.

6. The Janssen Order also makes clear that the documents can be used in future litigation: "In the event that the City of Chicago is a party to a legal proceeding against Janssen arising out of the Investigation, the City of Chicago may use and disclose as necessary the Produced Information, including Confidential Information, for the purpose of that proceeding or litigation consistent with applicable law." Ex. A ¶ 6.

7. The Confidentiality Agreements set forth a process for using Confidential Information in any subsequent litigation. The Janssen Order states: "All Confidential Information that is presented to the Court through argument, memoranda, pleadings or otherwise shall be submitted along with a motion for leave to file such information under seal pursuant to the rules of the Court." Ex. A ¶ 10. The Actavis Agreement provides: "If any party deems it necessary to use or disclose Protected Documents or any information contained therein in connection with any motion, the party's motion papers . . . shall be filed with the Protected Documents redacted. Copies to the court and to counsel of record shall have unredacted copies

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not subject to disclosure." Ex. B ¶ 11. The Teva Agreement defines "Protected Information" as information containing "trade secrets, proprietary or commercially sensitive information as defined by any court rule or state or federal statute (including information defined as 'trade secrets' in the Illinois Trade Secrets Act, 765 ILCS 1065), or Protected Health Information as such term is defined in 45 C.F.R.§ 160.13 ('Protected Information')." Ex. C ¶ 2.

of the Protected Documents." Ex. B ¶ 7. The Teva Agreement provides: "All Protected Information that is presented to the Court through . . . pleadings or otherwise shall be submitted along with a motion for leave to file such information under seal pursuant to the rules of the Court. . . ." Ex. C ¶ 9.

8. The Janssen Order also specifies that "The City of Chicago does not [in filing documents under seal] waive any claim that the information is not entitled to such treatment as Confidential Information." Ex. A ¶ 10. The Teva Agreement likewise provides: "The City of Chicago does not, in so doing, waive any claim that the information is not entitled to such treatment as Protected Information." Ex. C ¶ 9.

DISCUSSION

The Redacted Information Pertains to Matters of Public Interest

9. As a result of the Confidentiality Agreements, the City has filed its Complaint, redacting all references to documents that were produced during the Investigation with Confidential Information designations. The City believes, however, that these designations, are unfounded and overbroad, that the redacted information contains no trade secrets, or proprietary or commercially sensitive information, or any other confidential information, and that the public interest requires that this information be unsealed. Indeed, Cephalon, Endo, and Janssen, in particular, marked as "Confidential" nearly all of the documents they produced to the City during the Investigation. Some of the documents marked as "Confidential" include obviously public documents, such as copies of public advertisements; copies of published academic journal articles; brochures for public conferences which were written by other organizations; and even materials downloaded from the FDA website.

10. Thus, the City moves this Court to initially allow the unredacted Complaint to be

filed under seal, and, after the Sealed Complaint is reviewed in camera and determined not to contain protected information, issue an order unsealing the Sealed Complaint.

11. The request to unseal the Sealed Complaint is consistent not only with the Confidentiality Agreements, but also with the strong public policy favoring the transparency of judicial proceedings. The public's interest in disclosure is, as a general matter, compelling. "The common law right of access to court records is essential to the proper functioning of a democracy, in that citizens rely on information about our judicial system in order to form an educated and knowledgeable opinion of its functioning." *Skolnick*, 191 Ill. 2d at 230. This fundamental right to public courts has been codified under Illinois law. *See* 705 ILCS 105/16(6).

12. The public's interest in this case is even more powerful because, as outlined in the Complaint, the City, during its Investigation, uncovered the Defendants' scheme to misinform the health care community and consumers about the risks, benefits, and superiority of opioids when taken long-term to treat chronic non-cancer pain, causing a dramatic increase in opioid use and abuse in Chicago. This is not just a matter of academic interest; it affects the health and safety of the significant number of Chicago residents who are currently, or may begin, taking opioids for chronic non-cancer pain. These patients (or patients-to-be) and their doctors are entitled to accurate and complete information on Defendants' marketing practices so that they can make fully and truly informed decisions about the risks of using opioids.

13. The public's interest in openness is especially weighty in this case because the opioids marketed by Defendants are dangerous drugs, classified under the federal Controlled Substances Act as having "high potential for abuse" and a "risk of severe psychological and physical dependence," 21 U.S.C. § 812(b). They have subjected users to addiction, injury, and death. Moreover, Defendants have marketed these drugs with deceptive promotions aimed

specifically at vulnerable populations, such as the elderly and veterans, who face greater risks of adverse effects. The public has a right to know – and needs to know – about both the actual risks and the deceptive marketing of these drugs.

14. On the other side of scale, there is no compelling reason to keep the Complaint under seal. Nothing about the information designated as Confidential Information by Defendants and/or APF outweighs the public's compelling and presumptive right to access. The redacted sections of the Complaint include references to the creation of marketing materials; information chronicling Defendants' coordination with their front groups, including communications and donations; advertisements generated by or on behalf of Defendants; and materials that Defendants used to train their sales staff. The redacted information does not include trade secrets or proprietary or commercially sensitive information such as drug formulations, sales projections, or any other kind of information that should be shielded from disclosure and withheld from the public.

CONCLUSION

15. "[O]nce filed, the pleadings, motions and other papers filed with the court assume the presumption of public access . . . . 'Litigation is a public exercise; it consumes public resources. It follows that in all but the most extraordinary cases—perhaps those involving matters of weighty national security—complaints must be public.'" *Skolnick*, 191 Ill. 2d at 236–37, 730 N.E.2d at 19 (quoting *Levenstein v. Salafsky*, 164 F.3d 345, 348 (7th Cir.1998)). That presumption cannot be overcome in this case. As such, the unredacted Complaint should be unsealed.

RELIEF REQUESTED

WHEREFORE, the City respectfully requests that this Court:

a. Allow the unredacted Complaint to be initially filed under seal.

b. Issue an Order declaring that none of the documents or information discussed in the Complaint that has been deemed Confidential by Defendants is confidential.

c. Issue an Order unsealing the unredacted Complaint.

d. Grant such other and further relief as this Court deems necessary and appropriate.

Dated: June 2nd, 2014

Respectfully submitted,

STEPHEN R. PATTON
Corporation Counsel for the City of Chicago

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EXHIBIT A

IN THE CIRCUIT COURT OF COOK COUNT, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

THE CITY OF CHICAGO,

Petitioner,

v.

JANSSEN PHARMACEUTICALS, INC..

Respondent.

Docket No. 2013 L 010572

CONFIDENTIALITY STIPULATION AND PROTECTIVE ORDER

This confidentiality stipulation and protective order ("Protective Order") is entered into between the City of Chicago acting through its Department of Law and Janssen Pharmaceuticals, Inc. ("Janssen").

WHEREAS, on June 27, 2013, the Corporation Counsel for the City of Chicago served Janssen with a subpoena under Municipal Code of Chicago § 1-22-050 requesting certain documents in connection with its investigation into potential false claims submitted to the City of Chicago as a result of the marketing of opioid products (the "Investigation");

WHEREAS, the parties wish to facilitate the production of documents by Janssen to the City of Chicago while maintaining the confidentiality of the information that is requested by the subpoena;

NOW, THEREFORE, the City of Chicago and Janssen, through undersigned counsel, hereby stipulate and agree, and jointly request that the Court enter as an Order, the following Protective Order:

1. All information produced by Janssen in connection with the Investigation, including but not limited to information contained in documents or in correspondence between counsel ("Produced Information"), regardless of confidentiality designation, may only be used in accordance with the provisions of Municipal Code of Chicago § 1-22-050(i), or as otherwise required by law or court order.

2. Such Produced Information will be used solely for the purposes of the Investigation and any litigation or legal proceeding against Janssen brought by the City of Chicago and arising out of the Investigation. The Produced Information shall be held in confidence, and not disclosed or made known, by the City of Chicago except as provided by this Protective Order.

3. To the extent that Janssen produces any information that it believes, on a good faith basis, contains trade secrets, proprietary or commercially sensitive information (including information defined as "trade secrets" in the Illinois Trade Secrets Act, 765 ILCS 1065), or Protected Health Information as such term is defined in 45 C.F.R. § 160.103 ("Confidential Information"), Janssen shall mark or otherwise designate such material as "Confidential." "Confidential Information" includes not only information produced by Janssen, but also documents summarizing or derived from such information, including extracts, memoranda, notes, and correspondence quoting from or summarizing such information.

4. In the event that Janssen inadvertently fails to designate Confidential Information as confidential, it may make or amend such a designation subsequently by notifying, in writing, all parties to whom such material was produced. After receipt of such notification, the parties to whom production has been made shall treat the designated material as Confidential Information under the terms of this Protective Order. No party shall be deemed to have violated this Protective Order if, prior to notification of any subsequent designation, such information has been disclosed or used in a manner inconsistent with the subsequent designation.

5. The limitations on disclosure in this Protective Order of Produced Information, including Confidential Information, shall *not* apply to information where:

(a) the Corporation Counsel lawfully obtains the information from a source other than Janssen, provided that the Corporation Counsel is not aware that such source obtained or disclosed the materials in breach of any obligation of confidentiality;

(b) Janssen agrees in writing that the specific information can be disclosed;

(c) it has been ordered by a court of competent jurisdiction that specific information is not required to be kept confidential or does not constitute Confidential Information; or

(d) disclosure is otherwise required by law.

6. In the event that the City of Chicago is a party to a legal proceeding against Janssen arising out of the Investigation, the City of Chicago may use and disclose as necessary the Produced Information, including Confidential Information, for the purposes of that proceeding or litigation consistent with applicable law, provided, however, that the City of Chicago may not use or disclose Confidential Information, in any form, except as in accordance with paragraphs 7-10 below.

7. The City of Chicago may disclose Produced Information or Confidential Information pursuant to a valid, legally binding subpoena or civil investigative demand from a third party ("Third Party Request"); provided, however, that the Corporation Counsel shall provide Janssen reasonable notice before complying with the Third Party Request so that Janssen may seek a protective order. If the Third Party Request allows the Corporation Counsel fewer than ten (10) business days to respond, the Corporation Counsel's Office shall allow Janssen an equal amount of time to respond, less one day.

8. The City of Chicago acknowledges that Produced Information may contain trade secrets, proprietary or sensitive commercial information, or other confidential information, and that Janssen considers this information to be protected and exempt from disclosure under the Illinois Freedom of Information Act, Illinois public records laws, and any similar federal, state or municipal law ("Public Disclosure Laws"). If the City of Chicago receives a request made under the Public Disclosure Laws that it believes requires disclosure of any Produced Information, the Corporation Counsel will notify Janssen upon receipt of such request, so as to afford Janssen the opportunity to take steps to prevent disclosure; provided, however, that nothing in this Protective Order shall be read to conflict with the City of Chicago's duty to comply with the Public Disclosure Laws. The parties expressly note, however, that pursuant to Municipal Code of Chicago § 1-22-050(k), any documentary material, answers to written interrogatories, or oral testimony provided under the subpoena "shall be exempt from disclosure under the Illinois Administrative Procedure Act." Nothing in this Protective Order is intended to diminish the protections afforded to Janssen under this provision or authorize disclosure of information that would otherwise be prohibited under § 1-22-050.

9. In addition, the City of Chicago may disclose Produced Information to:

(a) employees of the City of Chicago Law Department that are participating in the Investigation and are bound by the terms of this Agreement;

(b) outside counsel at Cohen Milstein Sellers & Toll PLLC that are participating in the Investigation and agree to be bound by the terms of this Protective Order by signing the attached Exhibit A to this Protective Order. However, this provision shall not be construed as a waiver by Janssen of its previously-articulated objections to the involvement of Cohen Milstein in the Investigation;

(c) agents, independent consultants, contractors, and experts retained by, and other civil or criminal law enforcement divisions and agencies collaborating with, the Corporation Counsel in connection with this Investigation, provided that they agree to be bound by the terms of this Protective Order by signing the attached Exhibit A to this Protective Order, which includes an agreement to:

(i) be bound by the terms of this Protective Order to the same extent as the City of Chicago;

(ii) not disclose or otherwise use any Produced Information except for the benefit of Corporation Counsel in connection with this Investigation and in any litigation against Janssen brought by the City of Chicago arising out of the Investigation; and

(iii) return to Janssen all Produced Information in accordance with Municipal Code of Chicago § 1-22-050(i).

10. All Confidential Information that is presented to the Court through argument, memoranda, pleadings or otherwise shall be submitted along with a motion for leave to file such information under seal pursuant to the rules of the Court. Janssen may file whatever papers it deems appropriate in support of such motion for filing under seal. The City of Chicago does not,

in so doing, waive any claim that the information is not entitled to such treatment as Confidential Information.

11. If information subject to a claim of attorney-client privilege or work product protection or any other applicable privilege or protection from disclosure is mistakenly produced in response to the subpoena in the Investigation, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or protection for such information as provided under applicable law. If Janssen has mistakenly produced information subject to a claim of protection or privilege, and if Janssen makes a written request for the return of such information, the information for which a claim of mistaken production is made shall be returned, sequestered, or destroyed immediately and not used in the Investigation or any subsequent legal proceeding against Janssen, even if the City of Chicago disputes the claim of privilege or protection. If the City of Chicago disagrees with the claim of attorney-client privilege or work product protection or any other applicable privilege or protection, the City of Chicago may notify Janssen in writing stating the basis for its disagreement, and the parties shall confer in good faith as to this dispute. If the parties are unable to reach agreement, either party may bring a motion for a determination of whether the information is protected from disclosure. If such a motion is made, Janssen must, if directed by the Court, submit the information as to which a privilege is asserted to the Court for review in camera. This provision is intended to take advantage of the full scope of the protections provided by Illinois and Federal Rules of Evidence 502.

12. It is the responsibility of the City of Chicago to maintain all Produced Information in a secure manner so as to allow access to such information only to such persons and under such terms as permitted under this Protective Order.

13. The City of Chicago agrees to maintain the obligations of confidentiality imposed by this Protective Order following the conclusion of this Investigation and any subsequent litigation against Janssen related to the Investigation, to the extent permitted by law.

14. Nothing in this Protective Order shall prevent Janssen from any use of its own information produced in the Investigation, including Confidential Information.

15. The provisions of this Protective Order shall, absent further Order of the Court or the agreement of the parties, continue to be binding throughout and after the conclusion of the later of the Investigation or any subsequent litigation against Janssen brought by the City of Chicago arising out of the Investigation. Within sixty (60) calendar days after said date, including the exhaustion of all appeals, the City of Chicago shall destroy or return to Janssen all Produced Information, and certify to Janssen such destruction or return. However, the Corporation Counsel shall be entitled to retain all court submissions, trial transcripts, exhibits and attorney work product provided that any such materials containing Confidential Information are maintained and protected in accordance with the terms of this Protective Order.

16. The undersigned represent that they are duly authorized to enter into this Protective Order as counsel on behalf of the City of Chicago and Janssen, respectively.

Agreed to and accepted this 7th day of November, 2013.

Stephen R. Patton
Corporation Counsel

By: _____
Fiona A. Burke
Senior Counsel
Aviation, Environmental, Regulatory & Contracts Division
City of Chicago Department of Law

Janssen Pharmaceuticals Inc.

By: _____
Scott D. Stein
Michael P. Doss
Sidley Austin LLP
One South Dearborn Street
Chicago, IL 60603
Counsel for Janssen Pharmaceuticals Inc.

ENTERED
JUDGE SANJAY TAILOR-1870
NOV 12 2013
DOROTHY BROWN
CLERK OF THE CIRCUIT COURT
OF COOK COUNTY, IL
DEPUTY CLERK _____

SO ORDERED:

DATED: _____, 2013

By: _____
HON. SANJAY T. TAILOR
Circuit Court of Cook County

EXHIBIT B

LAW DEPARTMENT
CITY OF CHICAGO

IN THE MATTER OF	)	
	)	
CHRONIC OPIOID THERAPY PRACTICES	)	INVESTIGATIVE SUBPOENA
	)	

CONFIDENTIALITY AGREEMENT

The City of Chicago has served a subpoena on Actavis Inc. k/n/a Actavis LLC ("Actavis"), dated April 10, 2013 seeking documents and information ("Investigative Subpoena"), some of which may be confidential and proprietary. In order to preserve and maintain the confidentiality of certain documents to be produced or made available for inspection and copying, Actavis is entitled to have its confidential information protected. Therefore the parties have stipulated as follows:

1. Documents to be produced or made available for inspection and copying by Actavis to the City of Chicago in response to the Investigative Subpoena that contain confidential or proprietary information shall hereafter be referred to as "Protected Documents." When used in this Agreement, the word "documents" means all written material, data maintained in electronic or digital format, and all other tangible items. Except as otherwise indicated below, documents marked or otherwise designated by Actavis as "Confidential" that are produced or made available for inspection and copying by Actavis to the City of Chicago's attorneys, consultants, agents, or experts shall be Protected Documents and given confidential treatment as described in this Agreement. Immediately after inspection and before copying and before delivery to the City of Chicago's Counsel, Actavis shall mark as Confidential those documents that it believes, on a good faith basis, contain confidential or proprietary information, as defined by any applicable rule, or state or federal law.

2. Both the Protected Documents and the information contained therein shall be treated as confidential, shall not be disclosed except as provided in this Agreement, and shall be used solely for the purpose of this case, and not be made available to persons other than those described below. Other than Actavis, no party, other entity or person shall use any Protected Document or any information contained therein for any purpose other than the City of Chicago's investigation and any lawsuit that arises from that investigation.

3. The Protected Documents and any information contained therein shall not be shown, disseminated or disclosed to any person other than the following persons, except upon the prior written consent of Actavis or by order of a Court:

a. The City of Chicago's Law Department and their counsel of record and any other counsel, City employees or other law enforcement agencies associated to assist in the investigation;

b. Employees or contractors of counsel of record or of associated counsel, who assist in the investigation;

c. Experts and consultants retained by the parties in regards to this investigation;

d. A third party employed for the sole purpose of arranging for the copying and dissemination of the documents pursuant to this Agreement (i.e., a copy service).

4. Persons and entities described in any Paragraphs 3(a) through 3(d), above, who receive any Protected Document or any information contained therein under the terms of thisAgreement, shall not further disseminate any such Protected Document or information

contained therein, unless it is disseminated to another person or entity described in Paragraph 3(a)-(d) above.

5. All copies, whether digital or hard copy, of any Protected Document shall be subject to the terms of this Agreement.

6. Before being given access to any of the Protected Documents or any information contained therein, each person described in Paragraphs 3(c) and 3(d) above who is neither a party to or a counsel in the proceeding, shall be advised of the terms of this Agreement, shall be given a copy of this Agreement, and shall sign a copy of Exhibit A attached hereto, thereby acknowledging and agreeing to be bound by the terms of this Agreement.

7. If any party deems it necessary to use or disclose Protected Documents or any information contained therein in connection with any motion, the party's motion papers, including but not limited to memoranda, affidavits, and exhibits that contain or reference information contained in Protected Documents, shall be filed with the Protected Documents redacted. Copies to the court and to counsel of record shall have unredacted copies of the Protected Documents.

8. All Protected Documents shall be maintained under the control of and accounted for by the attorney, party or other entity or person receiving them.

9. In the event that Actavis inadvertently produces or discloses any document or information in this case without intending to waive a claim that it is confidential or privileged, such production or disclosure shall not be a waiver, in whole or in part, of a claim of confidentiality or privilege as to any such document or information. Within ten (10) days after Actavis actually discovers that such production or disclosure was made, Actavis shall provide written notice to the City of Chicago's counsel. The City of Chicago and all other parties,

entities and persons shall not review, copy or otherwise disseminate or disclose any of the specified documents or information following receipt of Actavis' notice, and shall return the specified documents and information and all copies thereof within ten (10) days of receipt of Actavis' notice.

10. This Agreement shall be binding upon the parties to this investigation and their counsel of record and all persons and entities signing a copy of the attached Exhibit A, and upon their attorneys, employees and agents.

11. Nothing in this Agreement constitutes a finding or admission that any Protected Document is in fact confidential, proprietary or otherwise not subject to disclosure. In the event of any dispute as to the propriety or correctness of the designation as a Protected Document, the parties shall attempt to resolve the dispute by negotiation. The burden of proof regarding whether any Protected Document is in fact confidential, proprietary or otherwise not subject to disclosure shall be on Actavis.

12. Given that the Protected Documents contain confidential, proprietary information, the parties acknowledge that any breach or threatened breach of the obligations hereunder will cause irreparable harm to Actavis and Actavis, having no other remedy at law, may go before a Court having jurisdiction over the parties, to seek to have such obligations specifically enforced and may seek, including without limitation, other injunctive relief and damages for the breach of this Agreement.

Dated this 3rd day of December, 2013.

By: _____

Linda Singer
Cohen Milstein Sellers & Toll PLLC
1100 New York Avenue, NW
Washington, DC 20005
as Special Assistant Corporation Counsel

EXHIBIT C

CONFIDENTIALITY AGREEMENT

This confidentiality agreement (the "Agreement") is entered into between the City of Chicago acting through its Department of Law and Teva Pharmaceutical Industries Ltd. ("Teva").

WHEREAS, the Corporation Counsel for the City of Chicago ("Corporation Counsel") issued a subpoena dated April 5, 2013 ("Subpoena"), which was subsequently served on Teva under Municipal Code of Chicago § 1-22-050 requesting certain documents in connection with its investigation into potential false claims submitted to the City of Chicago as a result of the marketing of opioid products (the "Investigation");

WHEREAS, the parties wish to facilitate the production of documents by Teva to the City of Chicago while maintaining the confidentiality of the information that is requested by the Subpoena;

NOW, THEREFORE, the City of Chicago and Teva, through undersigned counsel, hereby agree to the following:

1. All information produced by Teva in connection with the Investigation, including but not limited to information contained in documents or in correspondence between counsel ("Produced Information"), regardless of confidentiality designation or marking or lack thereof, may only be used in accordance with the provisions of Municipal Code of Chicago § 1-22-050(f), or as otherwise required by law or court order. When used in this Agreement, the word "documents" means all written material, data maintained in electronic or digital format, and all other tangible items. This Agreement also applies to all Produced Information provided by Teva in response to the Subpoena prior to the date of this Agreement.

2. To the extent that Teva produces any information that it believes, on a good faith basis, contains trade secrets, proprietary or commercially sensitive information as defined by any court rule or state or federal statute (including information defined as "trade secrets" in the Illinois Trade Secrets Act, 765 ILCS 1065), or Protected Health Information as such term is defined in 45 C.F.R. § 160.103 ("Protected Information"), Teva shall mark or otherwise designate such material as "Protected." "Protected Information" includes not only information produced by Teva, but also documents summarizing or derived from such information, including extracts, memoranda, notes, and correspondence quoting from or summarizing such information. Protected Information also includes documents produced by Teva in response to the Subpoena prior to the date of this Agreement that were designated as "Protected" or "Confidential."

3. In the event that Teva inadvertently fails to designate any Produced Information as Protected Information it may make or amend such a designation subsequently by notifying, in writing, Corporation Counsel within ten (10) days of learning of the oversight. After receipt of such notification, the parties to whom production has been made shall treat the designated material as Protected Information under the terms of this Agreement. No party shall be deemed to have violated this Agreement if, prior to notification of any subsequent designation, such information has been disclosed or used in a manner inconsistent with the subsequent designation.

(a) employees of the City of Chicago Law Department and its outside counsel that are participating in the Investigation and are bound by the terms of this Agreement;

(b) agents, independent consultants, contractors, and experts retained by, and other civil or criminal law enforcement divisions and agencies collaborating with, the Corporation Counsel in connection with this Investigation, provided that they agree to be bound by the terms of this Agreement by signing the attached Exhibit A to this Agreement.

9. All Protected Information that is presented to the Court through argument, memoranda, pleadings or otherwise shall be submitted along with a motion for leave to file such information under seal pursuant to the rules of the Court. Teva may file whatever papers it deems appropriate in support of such motion for filing under seal. The City of Chicago does not, in so doing, waive any claim that the information is not entitled to such treatment as Protected Information.

10. All Produced Information shall be maintained in accordance with the provisions of Municipal Code of Chicago § 1-22-050(l), or as otherwise required by law or court order.

11. If information subject to a claim of attorney-client privilege or work product protection or any other applicable privilege or protection from disclosure is mistakenly produced in response to the Subpoena in the Investigation, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or protection for such information as provided under applicable law. If Teva has mistakenly produced information subject to a claim of protection or privilege, and if Teva makes a written request for the return of such information to Corporation Counsel, the information for which a claim of mistaken production is made shall be returned, sequestered, or destroyed immediately and not used in the Investigation or any subsequent legal proceeding against Teva, even if the City of Chicago disputes the claim of privilege or protection. If the City of Chicago disagrees with the claim of attorney-client privilege or work product protection or any other applicable privilege or protection, the City of Chicago may notify Teva in writing stating the basis for its disagreement, and the parties shall confer in good faith as to this dispute. If the parties are unable to reach agreement, either party may bring a motion for a determination of whether the information is protected from disclosure. If such a motion is made, Teva must, if directed by the Court, submit the information as to which a privilege is asserted to the Court for review in camera. This provision is intended to take advantage of the full scope of the protections provided by Illinois and Federal Rules of Evidence 502.

12. The City of Chicago agrees to maintain the obligations of confidentiality imposed by this Agreement following the conclusion of this Investigation and any subsequent litigation against Teva related to the Investigation, to the extent permitted by law.

13. Nothing in this Agreement shall prevent Teva from any use of its own information produced in the Investigation, including Protected Information.

14. The provisions of this Agreement shall, absent an order of the court or the agreement of the parties, continue to be binding throughout and after the conclusion of the later

of the Investigation or any subsequent litigation against Teva brought by the City of Chicago arising out of the Investigation. Within sixty (60) calendar days after the later event described in the previous sentence, including the exhaustion of all appeals, the City of Chicago shall destroy or return to Teva all Produced Information. However, the Corporation Counsel shall be entitled to retain all court submissions, trial transcripts, exhibits and attorney work product provided that any such materials containing Protected Information are maintained and protected in accordance with the terms of this Agreement.

15. The undersigned represent that they are duly authorized to enter into this Agreement as counsel on behalf of the City of Chicago and Teva, respectively.

Agreed to and accepted this 25th day of March, 2014.

Stephen R. Patton
Corporation Counsel

By: _____
Fiona A. Burke
Senior Counsel
Aviation, Environmental, Regulatory & Contracts Division
City of Chicago Department of Law

Teva Pharmaceutical Industries Ltd.

By: _____
Tinos Diamantatos
Morgan, Lewis & Bockius LLP
77 West Wacker Drive
Chicago, IL 60601
Counsel for Teva Pharmaceutical Industries Ltd.

EXHIBIT A

I, _____ [full name], of _____ [company name and address], declare that I have read in its entirety and understand the Confidentiality Agreement between the City of Chicago and Teva Pharmaceutical Industries Ltd., entered into on March 25, 2014. I agree to comply with and be bound by all applicable terms of this Confidentiality Agreement. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Confidentiality Agreement to any person or entity except in strict compliance with the provisions of the Confidentiality Agreement, or unless required to do so by court order or other applicable law.

Date: _____

City and State: _____

Name: _____

Signature: _____

EXHIBIT D

ARNOLD & PORTER LLP

Joshua M. Davis
Joshua.Davis@aporter.com
+1 202.942.5743
+1 202.942.5999 Fax
555 Twelfth Street, NW
Washington, DC 20004-1206

November 14, 2013

VIA E-MAIL AND FEDERAL EXPRESS

NOV 18 2013

Michael Dolesh, Esquire
Fiona Burke, Esquire
City of Chicago
Department of Law
City Hall, Room 600
121 North LaSalle Street
Chicago, IL 60602

Linda Singer, Esquire
Cohen Milstein Sellers & Toll PLLC
1100 New York Avenue, N.W.
Suite 500, West Tower
Washington, DC 20005

Re: Endo Health Solutions Inc.

Dear Mr. Dolesh, Ms. Burke and Ms. Singer:

In response to the Investigative Subpoena, dated May 29, 2013, served by the City of Chicago on Endo Health Solutions Inc. ("Endo") ("Subpoena") and further to our recent discussions, enclosed is a DVD labeled "Endo Pharmaceuticals Inc. ENO001." The DVD contains documents responsive to the Subpoena. Those documents bear the Bates Numbers ENO00000001 to END00004427.

As we discussed during our call of November 13, 2013, pending the execution of a mutually agreeable confidentiality agreement, we are producing these documents based on the verbal commitments regarding confidentiality that the City of Chicago and Cohen, Milstein extended during that call. Upon execution of a mutually agreeable confidentiality agreement, the enclosed documents will be subject to the terms of that agreement.

Please let us know if you have any questions or comments or if we can be of further assistance at this point. As always, we are happy to discuss. Thanks for your attention.

Sincerely,

Joshua M. Davis

EXHIBIT E

CONFIDENTIAL

NON-DISCLOSURE AGREEMENT

I, Linda Singer, Special Assistant Corporation Counsel for the City of Chicago and on behalf of Cohen Milstein Sellers & Toll PLLC, understand that the documents, materials and information provided by the American Pain Foundation to the City of Chicago ("Documents") pursuant to its civil Investigative Demand are confidential. I further understand that any such Documents may include trade secrets or other proprietary or confidential information that are exempt from public disclosure. I agree to implement reasonable measures to protect the confidentiality and security of the Documents and not to disclose any of the information or Documents provided to me to a third party, with the exception of other law enforcement agencies, unless authorized by the American Pain Foundation or required to do so by court order or other applicable law.

Date: April 3, 2013

Reviewed and Agreed:

Linda Singer, Esq.
Cohen Milstein Sellers & Toll PLLC
1100 New York Avenue, NW
Suite 500, West Tower
Washington, DC 20005

Special Assistant Corporation Counsel for the City of Chicago